2021

TECHNICAL FILE

CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST

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Rapid Test Device

Intended Use

In this kit is used for the in vitro qualitative detection of SARS-CoV-2 antigen. This test is for clinical laboratory use or emergency medical examination only, not for home testing. It cannot be used as a basis for pneumonia caused by a new coronavirus infection. A positive test result must be further confirmed. The kit and test results are intended for clinical reference only.

Principle

This reagent uses a lateral flow immunoassay to legally detect the antigen of the new coronavirus (SARS-CoV-2) in nasopharyngeal swab samples. During detection, the gold-marked anti-SARS-CoV-2 monoclonal antibody in the marking pad binds to the SARS-CoV-2 antigen in the sample to form a complex and the reaction complex moves forward across the nitrocellulose membrane. It is captured by the anti-SARS-CoV-2 monoclonal antibody pre-coated with the detection zone (T) on the chromatography membrane and finally a red colored reaction line is formed in the T zone. The SARS-CoV-2 antigen cannot create a red colored reaction line in the T region. Regardless of whether the sample to be tested contains the SARS-CoV-2 antigen or not, a red reaction line will always appear in the quality control area (C).

Manufacturer Overview

Vision Biotechnology company was established in 2019, and by producing "Domestic Test Kit" during the pandemic period, it accelerated the development of our company with its R&D studies and achieved a success beyond expectations with the test kits it produced both in the Turkish market and in the global market. Vision Biotechnology has ISO 13485 certification. Our company produces diagnostic kits, rapid diagnosis kits, PCR test kits and GMO detection kits according to the needs of the sectors. The company complies with the EC declaration of conformity in accordance with directive 98/79/EC.

Performance Characteristics

Sensitivity and Specificity

The SARS Cov-2 Rapid Test Kit was administered on 299 nasal swabs collected from symptomatic patients who developed symptoms within 7 days. A limited number of patients with symptoms for more than 7 days and asymptomatic patients were included in the clinical study (n = 304). The sample size was relatively significant, with 99.3% positive agreement (302/304) and 98.8% negative agreement (445/450). The test is designed for professional use.

Check Up SARS-CoV-2 Nasal Antigen Rapid Test	**Comparative RT-PCR test results**		
	Positive (+)	**Negative (-)**	**Total**
Positive	302	5	307
Negative	2	445	447
Total	304	450	754
Sensitivity: 302/304 99,3 %, (95% CI: 95.82,98.51)			
Specificity: 445/450 98,8%, (95% CI:97.81, 99.69)			

Cross-reactivity

The cross-reactivity of the kit was assessed. The results showed no cross-reactivity with the following examples. HCoV-HKU1,Staphylococcus aureus,Streptococcus pyogenes,Measles virus,Paramyxovirus parotitis,Adenovirus 3,Mycoplasma pneumonia,Parainfluenza virus 2,Human Metapneumovirus(Hmpv),Human coronavirus OC43,Human coronavirus NL63,Human coronavirus 229E,MERS Coronavirus,Bordetella parapertussia,Influenza B (Victoria strain),Influenza B (Ystrain),Influenza A (H1N1 2009),Influenza A (H3N2),Avian influenza virus (H7N9),Avian influenza virus (H5N1),Epstein-Barr virus,Enterovirus CA16,Rhinovirus,Respiratory syncytial virus (RSV),Streptococcus pneumonia,Candida albicans,Chlamydia pneumonia,Bordetella pertussis,Pneumocystis jirovecii,Mycobacterium tuberculosis,Legionella pneumophila,

Interfering Substances

The test results are not affected with the substance at the following concentration.

Whole Blood(4%); Ibuprofen (1 mg/ml); Tetracycline (3µg / ml), Chloramphenicol (3µg/ l);Erythromycin (3µg/ml);Tobramycin(5%);Throat spray Menthol 5%;Mupirocin10mg/ml;Throat lozenge（Menthol1.5mg/ml;Tamiflu (Oseltamivir)5mg/ml;Naphthoxoline Hydrochloride nasal drops 15%;Mucin 0.50%;Fisherman's Friend 1.5mg/ml;Compound Benzocaine Gel 1.5mg/ml; Cromoglycate 15%; Sinex (Phenylephrine Hydrochloride) 15%; Afrin (Oxymetazoline) 15%;Fluticasone propionate spray 15%.

Validation Studies

1.Research Summary

Clinical institutions conduct clinical validation tests on products CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST (Hereinafter referred to as assessment reagent) which is registered for the first time. Proving the clinical performance of the assessment reagent meets the expected requirements. Medlife Laboratories from four different sites in Turkey (Istanbul, Kocaeli, Sakarya and Duzce) have tested n=754 samples for the SARS-CoV-2 virus with the CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST Kit of the manufacturer Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sistemleri San. ve Tic. LTD ŞTİ. There were 304 samples in the case group. In total 302 out of 304 true positive samples (verified by PCR) were tested as positive by the assessment reagent. The control group consisted of 450 true negative samples (verifed by PCR); 445 samples were tested as negative by the assessment reagent. Clinical diagnosis results of assessment reagents:

The sensitivity was 99.3%, the specifcity was 98.8%.

2 Basic Content

2.1 Test purpose

The intention of the laboratory tests was to validate the performance of the test product by direct comparison with PCR based test results.

2.2 Introduction

SARS-CoV-2, also known as the Covid- 19 virus, causes an acute respiratory infectious disease. Humans are generally susceptible. The main source of infection is currently people infected with the virus, including those who have an asymptomatic course.

The incubation period varies according to current epidemiological studies between 1 and 14 days, but usually between 3 and 7 days. Typical symptoms of manifestation include fever, fatigue and dry cough. Among others, rhinorrhea, sore throat, myalgia & diarrhea symptoms may occur in rare cases.

2.3 Trial design

2.3.1 Description of the overall design and plan of the test

This experiment was based on blind and control methods. The samples from confirmed patients infected with novel coronavirus, were selected for blind detection by the test reagent.

The test results were compared with the PCR results, and the feasibility of application of test reagent in clinical practice was evaluated by judging the clinical sensitivity of the test reagent. Before starting the tests, employees were familiarized with the handling of the test product in accordance with the instructions in the operating manual, in order to reduce investigator-dependent errors to a minimum.

2.3.1.1 The general process

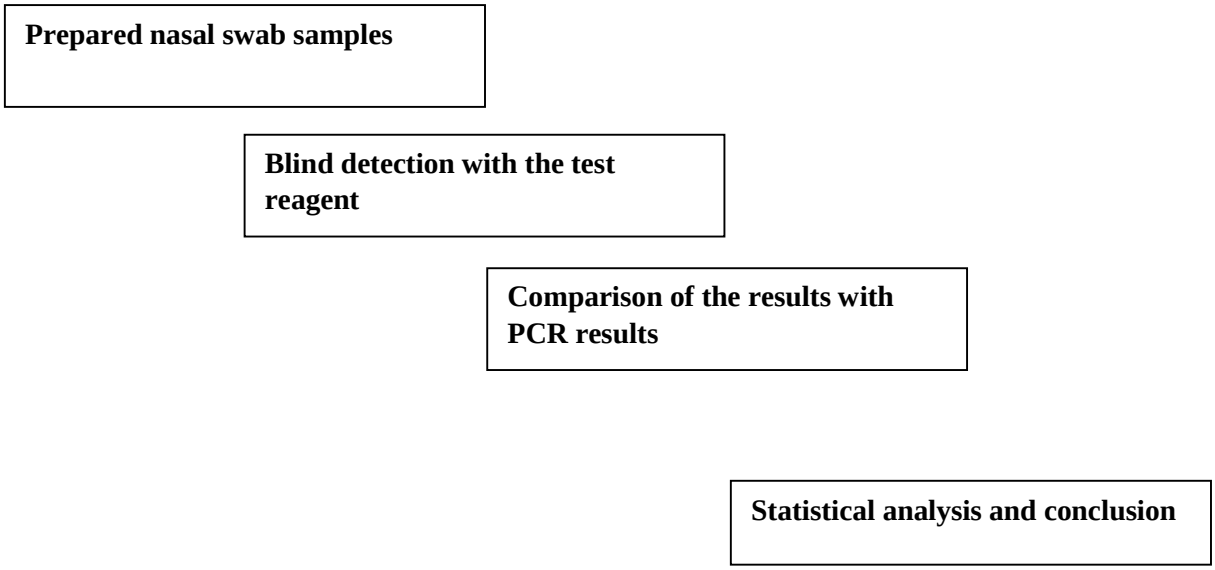
(a) In a first step, nasal swab samples were prepared in institutes.

(b) The blank test was performed with the test reagent and the test results were recorded.

(c) Each invalid result was retested. If the result was still invalid, the test was marked as invalid.

(d) Finally, the results of the test reagent and PCR were statistically evaluated.

2.3.1.2 Test process flow chart



3. Test design and test method

3.1 Sample selection basis, criteria of inclusion, exclusion and elimination

3.2 Selection basis

A total of 754 samples were tested for Sars Covid 19-2 by the clinical facilities of the Medlife laboratories using real-time polymerase chain reaction (RT-PCR). N=304 samples were Sars Covid 19-2 positive. N=450 cases formed the control group, consisting of only RT-PCR negative samples.

The samples selected are nasal swab specimens from patients with suspected or confirmed novel coronavirus infection. (RT PCR samples were obtained as nasal)

According to the clinical information, the patients were divided into a case group and a control group.

Case group: samples of patients diagnosed with coronavirus infection based on the "Diagnostic and treatment plan for pneumonia caused by a new coronavirus infection", including samples of subjects without clinical symptoms.

Control group: samples from patients not infected with the novel coronavirus.

3.2.1 Criteria for sample inclusion

(1) Age limit;

(2) No gender limit;

(3) Complete information file, including clinical status (case (symptomatic/ asymptomatic) and control), sample ID number, name, gender, age, department, PCR result, sample type and sampling date.

3.2.2 Criteria for sample exclusion

(1) Samples that have been repeatedly frozen and thawed for more than 3 times;

(2) A sample with incomplete information;

(3) A sample of duplicate cases.

3.2.3 Criteria for sample elimination

(1) Samples that fail to meet the inclusion criteria and included by mistake.

(2) Samples that meet the inclusion criteria but fail to meet the test plan due to contamination during sample preservation or insufficient sample size caused by human error after inclusion.

4. Establishment of Reference Methods

The clinical evaluations were compared with the PCR results and the clinical sensitivity and specificity of the assessment reagents were evaluated.

4.1. Product Information for clinical evaluations assessment reagent

Reagent name: CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST

Catalog number: C2104N01 Expiry date: 2022.01

Storage conditions: 2 - 30^{o}C

4.2. The information of clinical unit

Hospital: Medlife Laboratories Duzce

Address: Kiremit Ocagi Dst. Haci Bilal St. N:3, Duzce, Turkey

5. Method of quality control

In the course of the validation phase, care was taken to ensure that the tests with the assessment reagent were performed in a uniform manner. Methods and assessment standards were harmonized. The entire testing process was strictly standardized. The tester

recorded the test results faithfully and carefully. All observations and findings in the clinical evaluation were reviewed to ensure the reliability of the data and that the conclusions in the clinical evaluation can be derived from the original data. Appropriate data management measures were in place during the clinical evaluation and data processing phase.

6. Statistical analysis method of clinical evaluation data

Statistical analysis was conducted to summarize the results in the form of a four-lattice table and based on this, clinical sensitivity, clinical specificity including the confidence-interval (95% CI) were calculated.

6.1. Modi cation of scheme during test

None

7. Clinical evaluation results and analysis

7.1 Statistics of test reagent results and PCR results on nasopharyngeal swab samples

7.2 Statistical results

	Comparative RT-PCR test results		
	Positive (+)	**Negative (-)**	**Total**
Positive	302	5	307
Negative	2	445	447
Total	304	450	754
Sensitivity: 302/304 99,3 %, (95% CI: 95.82,98.51)			
Specificity: 445/450 98,8%, (95% CI:97.81, 99.69)			

8. Discussion and conclusion

The CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST has been validated. The testing process was carried out strictly according to the clinical evaluation plan and standard operating procedures. The performance of the above-mentioned CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST is considered satisfactory.

8.1. Description of special conditions in clinical evaluations

None.

Stability Study

1. Purpose

To investigate the performance of the CHECK UP Sars- CoV-2 Nasal Antigen Rapid Test device under the influence of normal temperature and high temperature storage conditions over time, which is the production, packaging, storage, transportation conditions and expiration date of the kit. The determination provides a scientific basis to ensure the safety and effectiveness of this kit.

2. Determination of stability

Refer to the expiration date of the marketed product and combine with the actual situation of the company's kit to conduct a stability test. The test results obtained serve as the initial basis for determining the expiration date of this kit. The tentative validity period of this kit is: store at 2-30℃,30 RH in the dark for 24 months. The studies were managed by the laboratory supervisor. Study results were checked and approved by the quality director and general manager.

3. Real Time Stability Evaluation

3.1. Testing Items

Items	**Requirements**
Negative Coincidence Rate	Use the Rnase-Dnase free water for internal negative control, N1-N5 for testing, requiring products to be negative.
Positive Coincidence Rate	Use the company's positive control A1-A5 for testing, requiring products to be negative.
Running time	C line appearing time＜60"
Product Background	Background clear, not affect the interpretation of results

3.2 Investigation Time and Time Interval Setting

For the test kit, the targeted shelf life is 24 months. The stability study of the assay is designed to provide data for a 10% longer timeframe than our targeted shelf life. For this reason, the real-time stability study period is planned as 27 months. Real-time stability study was carried out between 1.04.2020 and 30.07.2022. The real-time stability study plan is as follows.

Real Time Stability Study													
Study point		1	2	3	4	5	6	7	8	9	10	11	12
Time point	25 ℃	0 day	1st month	4th month	7th month	10th month	13th month	16th month	19th month	22th month	25th month	26th month	27th month

In the real-time stability study, it was planned to run 5 negative and 5 positive samples on the above dates. Kit testing of samples was done in 2 parallels. NA1, NA2 show two parallel results of the same negative sample. In positive samples, A1A, A1B show two parallel results of the

same positive sample. The positive control sample is the positive patient sample diluted at 3xLOD level. Positive patient sample was obtained from Medlife Laboratory.
In the real-time stability study, it was carried out in the Vision Biotechnology R&D Laboratory, in the air-conditioning test cabinet of the Nüve brand, TK252 model, at a storage temperature of 25°C and a humidity of 50rH. The tests were carried out by laboratory experts and approved by the laboratory supervisor.

3.3 LOT of stability study product

Using 3 consecutive batches of products, LOT: CN2105N01, CN2105N02,CN2105N03

3.4 Package and storage conditions

The packaging of the long-term stability test of this kit is the same as the packaging to be marketed. 2~30℃ storage.

3.5 Setting of investigation time and time interval

Store the reagent to be tested under the required storage conditions (25 ℃). If the temperature exceeds the required range, adjust it. Remove the reagent from the incubator every specified number of days. In the real-time stability study, N1-N5 samples in the negative panel and A1-A5 samples in the positive panel were studied on the dates in the plan. The determination time of the C line was followed in the studies. T-line density was determined using Sigma's 50 bp DNA Step Ladder, product containing fragments of 50 to 500 bp repeats.

3.6 Real Time Stability Study Data and Results

0-day Result

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+

C line appearing time:≤60", T line density:35,1", intensity of the T-line change: 150-200 bp Conclusion: Conformity.

1st month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:35,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

4th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+

	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
C line appearing time:≤60", T line density:36", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

7th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:38", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

10th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-

	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:41,3", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

13th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:41,10" Conclusion: Conformity.					

16th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-

	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:41,12" Conclusion: Conformity.					

19th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
C line appearing time:≤60", T line density:41,90" Conclusion: Conformity.					

22th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027			
	N1B	CN027			

	N2A	CN027			
	N2B	CN027			
	N3A	CN027			
	N3B	CN027			
	N4A	CN027			
	N4B	CN027			
	N5A	CN027			
	N5B	CN027			
Positive Reference panel	A1A	CN085			
	A1B	CN085			
	A2A	CN085			
	A2B	CN085			
	A3A	CN085			
	A3B	CN085			
	A4A	CN085			
	A4B	CN085			
	A5A	CN085			
C line appearing time: T line density: Conclusion: Studies continue.					

25th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027			
	N1B	CN027			
	N2A	CN027			
	N2B	CN027			
	N3A	CN027			
	N3B	CN027			
	N4A	CN027			
	N4B	CN027			
	N5A	CN027			
	N5B	CN027			
Positive Reference panel	A1A	CN085			
	A1B	CN085			
	A2A	CN085			
	A2B	CN085			
	A3A	CN085			
	A3B	CN085			
	A4A	CN085			
	A4B	CN085			
	A5A	CN085			
C line appearing time: T line density: Conclusion: Studies continue.					

26th month

Reference Panel	LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03

Negative Reference panel	N1A	CN027			
	N1B	CN027			
	N2A	CN027			
	N2B	CN027			
	N3A	CN027			
	N3B	CN027			
	N4A	CN027			
	N4B	CN027			
	N5A	CN027			
	N5B	CN027			
Positive Reference panel	A1A	CN085			
	A1B	CN085			
	A2A	CN085			
	A2B	CN085			
	A3A	CN085			
	A3B	CN085			
	A4A	CN085			
	A4B	CN085			
	A5A	CN085			
C line appearing time: T line density: Conclusion: Studies continue.					

27th month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027			
	N1B	CN027			
	N2A	CN027			
	N2B	CN027			
	N3A	CN027			
	N3B	CN027			
	N4A	CN027			
	N4B	CN027			
	N5A	CN027			
	N5B	CN027			
Positive Reference panel	A1A	CN085			
	A1B	CN085			
	A2A	CN085			
	A2B	CN085			
	A3A	CN085			
	A3B	CN085			
	A4A	CN085			
	A4B	CN085			
	A5A	CN085			
C line appearing time: T line density: Conclusion: Studies continue.					

4.Accelerated stability

Accelerated stability study is a method used to determine the shelf life in a short time by exposing the product to variables such as high temperature or humidity, accelerating the deterioration of the product.

The concept of accelerated stability testing is based on the Arrhenius equation, which describes the relationship between storage temperatures and degradation rate:

ln K= ln A + Δ E / RT

K = decay rate/s,

A = frequency factor/s, (It deals specifically with molecular collision, deals with the frequency of molecules colliding in the right direction and with enough energy to initiate a reaction.

ΔE = activation energy (kJ/mol),

R = universal gas constant (0.00831kJ/mol),

T= absolute temperature (K)

The calculation is done as follows.

Shelf Life Calculation

FACTOR (F):2 $^{[TAA\text{-}TRT/10]}$

TAA = accelerated aging temperature

TRT = Room temperature

4.1 Testing items

Items	**Requirements**
Negative Coincidence Rate	Use the Rnase-Dnase free water for internal negative control, N1-N5 for testing, requiring products to be negative.
Positive Coincidence Rate	Use the company's positive control A1-A5 for testing, requiring products to be negative.
Running time	C line appearing time＜60”
Product Background	Background clear, not affect the interpretation of results

4.2. Investigation time and time interval setting

The accelerated aging technique is based on the assumption that the chemical reactions associated with the deterioration of materials follow the Arrhenius reaction rate function. This function indicates that a temperature increase of 10°C will double the chemical reaction rate. If the reaction rate doubles Q10 = 2. The targeted shelf life for the test is 24 months. Accordingly, 55 °C and 50 RH humidity were applied for the accelerated shelf life study. Studies were carried out by exposure to high temperature and humidity.

Accelerated shelf life study was carried out in the Nüve brand TK252 air conditioner test cabinet at Vision Biotechnology R&D Laboratory. The tests were carried out by laboratory experts and approved by the laboratory manager. At the times programmed below, each 10 test was removed from the conditioning cabinet and tested with 5 positive and 5 negative

samples. Kit testing of samples was done in 2 parallels. NA1, NA2 show two parallel results of the same negative sample. In positive samples, A1A, A1B show two parallel results of the same positive sample.

Shelf life = Working time x Factor
Factor (F):$2^{[TAA-TRT/10]}$ $=2^{(55-25)/10}=2^3=8$ Since the shelf life is 2 years, it is 730 days.
730= Working time x 8=91,25 days ~92 days
The accelerated shelf life study will continue for 92 days. In the study, the aforementioned vocalization is made with the Arrhenius equation and its shelf life. Fast stable work can be realized on 1.04.2020 01.06.2020. It's like real-time endurance training.

Accelerated Stability Study										
Study point		1	2	3	4	5	6	7	8	9	10
Time point	55℃	0 day	9th day	16th day	31th day	53th day	68th day	80th day	85th day	90th day	92th day

In the accelerated stability study, the positive control sample used in the real-time stability study was used. The positive control sample is the positive patient sample diluted at 3xLOD. Positive patient sample was obtained from Medlife Laboratory. The real-time stability study was carried out in the Vision Biotechnology R&D Laboratory, in a Nüve brand, TK252 model air-conditioning test cabinet. The tests were carried out by laboratory experts and approved by the laboratory supervisor.

4.3 LOT of stability study product
Using 3 consecutive batches of products, LOT: CN2105N01, CN2105N02, CN2105N03

4.4 Package and storage conditions

The packaging of the long-term stability test of this kit is the same as the packaging to be marketed.

4.5 Setting of investigation time and time interval
In the accelerated stability study, N1-N5 samples in the negative panel and A1-A5 samples in the positive panel were studied on the dates in the plan. The determination time of the C line was followed in the studies. T-line density was determined using Sigma's 50 bp DNA Step Ladder, product containing fragments of 50 to 500 bp repeats.

4.5 Stability study data and results
0-day Result

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-

	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:35,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

9th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:36,2", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

16th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
	N1A	CN027	-	-	-

Negative Reference panel	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:36,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

31th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:37,3", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

53th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:38,2", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

68th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+

	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:40,2", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

80th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:46,1", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

85th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	N1A	CN027	+	+	+
	N1B	CN027	+	+	+
	N2A	CN027	+	+	+
	N2B	CN027	+	+	+

	N3A	CN027	+	+	+
	N3B	CN027	+	+	+
	N4A	CN027	+	+	+
	N4B	CN027	+	+	+
	N5A	CN027	+	+	+
	N5B	CN027	+	+	+
C line appearing time:≤60", T line density:46,5", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

90th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:46,7", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

92th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-

Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:47,2", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

5. Conclusion The novel coronavirus is a newly discovered virus. The company began research and development in early February 2020.Based on the market demand of the product, it is urgently needed to be listed, but due to the short time, long-term stability is not sufficient to support product stability. But according to the acceleration stability, the product can support the validity period of 24 months, so this product meets the market demand based on the acceleration stability result of the product.

B. STORAGE AND STABILITY

1.Purpose

The aim of this study is to investigate the performance of the CHECK UP Sars- CoV-2 Nasal Antigen Rapid Testdevice under the influence of high, low and normal temperature conditions of the kit, packaging, storage conditions.

2.Determination of stability

Refer to the expiration date of the marketed product and combine with the actual situation of the company's kit to conduct a stability test. The test results obtained serve as the initial basis for determining the expiration date of this kit. The tentative validity period of this kit is: store at 2-30℃, 30 RH in the dark for 24 months. The studies were managed by the laboratory supervisor. Study results were checked and approved by the quality director and general manager.

3. Real Time Stability Evaluation

3.1. Testing Items

Items	**Requirements**
Negative Coincidence Rate	Use the Rnase-Dnase free water for internal negative control, N1-N5 for testing, requiring products to be negative.
Positive Coincidence Rate	Use the company's positive control A1-A5 for testing, requiring products to be negative.
Running time	C line appearing time＜60"
Product Background	Background clear, not affect the interpretation of results

3.2 Investigation Time and Time Interval Setting

In order to check the suitability of the storage conditions of the test kit, a 28-day study was planned. The kit has been exposed to different storage temperatures. The kit is according to the following plan; It was studied with 5 positive and 5 negative samples at high, low and normal storage temperatures. Kit testing of samples was done in 2 parallels. NA1, NA2 show two parallel results of the same negative sample. In positive samples, A1A, A1B show two parallel results of the same positive sample. Storage stability study; It was held between 1.04.2020 - 1.05.2020. Refer to the table below, take out the specimen at the specified time, leave it at room temperature for 30 minutes, and then test the corresponding specimen according to the package insert.

Storage Stability Study					
	1 point	2 point	3 point	4 point	5 point
Room temperature	1 hour	2th hour	N/A	N/A	N/A
2 to 8 ℃	1day	2th day	3th day	4th day	N/A
-20℃	3th day	7th day	14th day	21th day	28th day

It is planned to run 5 negative and 5 positive samples on the above dates in the storage stability study. The positive control sample is the positive patient sample diluted at 3xLOD. A positive patient sample was obtained from Medlife Laboratory.

The real-time stability study was carried out in the Vision Biotechnology R&D Laboratory, in the Nüve brand TK252 air conditioner test cabinet. The tests were carried out by laboratory experts and approved by the laboratory manager.

3.3 LOT of stability study product

Using 3 consecutive batches of products, LOT: CN2105N01, CN2105N02, CN2105N03

3.4 Package and storage conditions

The packaging of the storage stability test of this kit is the same as the packaging to be marketed. 2~30℃ storage.

3.5 Setting of investigation time and time interval

Refer to the table below, take out the specimen at the specified time, leave it at room temperature for 30 minutes, and then test the corresponding specimen according to the package insert.

3.6 Results of experiment data

Data of experiment results

Room temperature; for 1 hour

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-

	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:35,2", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

Room temperature; for 2th hour

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:36,3", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

2-8°C temperature; for 1 day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:37,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

2-8°C temperature; for 2th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+

	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:37,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

2-8°C temperature; for 3th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:37,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

-20°C temperature; for 3th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+

	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:38,3", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

-20°C temperature; for 7th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:38,5"", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

-20°C temperature; for 14th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
	A1A	CN085	+	+	+

Positive Reference panel	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:38,9", intensity of the T-line change: 150-200 bp Conclusion: Conformity.					

-20°C temperature; for 21th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-
	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:39,2", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

-20°C temperature; for 28th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02	LOT:CN2105N03
Negative Reference panel	N1A	CN027	-	-	-
	N1B	CN027	-	-	-
	N2A	CN027	-	-	-
	N2B	CN027	-	-	-
	N3A	CN027	-	-	-
	N3B	CN027	-	-	-
	N4A	CN027	-	-	-

	N4B	CN027	-	-	-
	N5A	CN027	-	-	-
	N5B	CN027	-	-	-
Positive Reference panel	A1A	CN085	+	+	+
	A1B	CN085	+	+	+
	A2A	CN085	+	+	+
	A2B	CN085	+	+	+
	A3A	CN085	+	+	+
	A3B	CN085	+	+	+
	A4A	CN085	+	+	+
	A4B	CN085	+	+	+
	A5A	CN085	+	+	+
	A5B	CN085	+	+	+
C line appearing time:≤60", T line density:40,5", intensity of the T-line change: 100-150 bp Conclusion: Conformity.					

4. Conclusion

The above results show that the specimen is stable when store at room temperature for 2 hours, at 2 to 8℃ for 4 days and -20℃ for 28 days.

C.TRANSPORT SIMULATION STABILITY STUDY

1.Purpose

The purpose of this study is to investigate the transport stability performance of the VISION Covid-19 Rapid Antigen Test Kit.

2.Determination of stability

To do a stability test, look at the marketed product's expiration date and combine it with the actual condition of the company's kit. The test results obtained serve as the starting basis for determining the expiration date of this kit. Transport stability studies of this kit were directed by the laboratory supervisor. Study results were checked and approved by the quality director and general manager.

3. Transport Stability Evaluation

3.1. Testing Items

Items	**Requirements**
Negative Coincidence Rate	Use the Rnase-Dnase free water for internal negative control, N1-N5 for testing, requiring products to be negative.
Positive Coincidence Rate	Use the company's positive control A1-A5 for testing, requiring products to be negative.
Running time	C line appearing time＜60"
Product Background	Background clear, not affect the interpretation of results

3.2 Investigation Time and Time Interval Setting

For the test kit, the targeted shelf life is 24 months. The stability study of the assay is designed to provide data for a 10% longer timeframe than our targeted shelf life. For this reason, transport stability study period is planned as 27 months. Transport stability study was carried out between 1.04.2020 and 30.07.2022. N1-N5 samples in the negative panel and A1-A5 samples in the positive panel were studied on the dates in the plan. The determination time of the C line was followed in the studies. T-line density was determined using Sigma's 50 bp DNA Step Ladder, product containing fragments of 50 to 500 bp repeats. For each lot, with maintenance of 5 positive and 5 negative. The kit test of the samples was done in 2 parallels. NA1 does not show the same negative two things parallel NA2. In positive samples, A1A, A1B show the same two positive two parallel. The positive control sample is the positive patient sample diluted at 3xLOD. A positive patient sample was obtained from Medlife Laboratory. The transport stability study was carried out in the Vision Biotechnology R&D Laboratory, in the Nüve brand TK252 air conditioner test cabinet. The tests were carried out by laboratory experts and approved by the laboratory manager.

a. 3XFT: Perform 3 freeze/thaw cycles and at the last thaw, transfer to the recommended storage temperatures in the insert or designate temperature (generally store at retain room(2-30℃) for the remainder of the study.(Freeze: keep the goods in refrigerator for 48 hours (at least);Thaw: take the goods from refrigerator and keep it in room temperature at least 8 hours).

b. 2 Days @ 55℃: Place test strips in a 55℃ conditioner test cabinet for 2 days and transfer to the recommended storage temperatures in the insert or designate temperature (generally store at retain room (2-30℃)for the remainder of the study. Following table illustrate the designated time points when the stability test will be performed.

The transport stability study plan is as follows:

Transport Simulation	Day			Month						
	0	30**	60**	6*	12*	18*	21*	24*	25*	27*
3XFT	X	X	X	X	X	X	X	X	X	X
2 Days @ 55℃	X	X	X	X	X	X	X	X	X	X

- 0 day is the time before the products were taken from the designated challenged environment.
- Test time point date(day)=the date of “0 day” + the time of “**”
- Test time point date(month)=manufacture date + the time of “*”
- Every test point date should be preset.
- Product need to remove from the designed environment and completed the test within a week when a time point reached.
- The test time point of target expiry date must be added in the schedule.

3.3 LOT of stability study product

Using 2 consecutive batches of products, LOT: CN2105N01, CN2105N02

3.4 Setting of investigation time and time interval

Refer to the table below, take out the specimen at the specified time, leave it at room temperature for 30 minutes, and then test the corresponding specimen according to the package insert.

3.5 Results of experiment data

Data of experiment results

3XFT; 0 day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:42,5", intensity of the T-line change: 150-200 bp Conclusion: Conformity.				

3XFT; 30th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
	A1A	CN085	+	+

Positive Reference panel	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:44,3", intensity of the T-line change: 150-200 bp Conclusion: Conformity.				

3XFT; 60th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:44,6", intensity of the T-line change: 150-200 bp Conclusion: Conformity.				

3XFT; Month 6

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-

	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:45,1", intensity of the T-line change: 150-200 bp Conclusion: Conformity.				

3XFT; Month 12

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:45,7", intensity of the T-line change: 150-200 bp Conclusion: Conformity.				

3XFT; Month 18

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-

	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:47,2", intensity of the T-line change: 100-150 bp Conclusion: Conformity.				

3XFT; 21 month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density: Conclusion: Studies continue.				

3XFT; 24 month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density: Conclusion: Studies continue.				

3XFT; Month 25

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		

C line appearing time: T line density: Conclusion: Studies continue.

3XFT; 27 month

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density: Conclusion: Studies continue.				

2 days at 55°C- 0 day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+

	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:43,4" Conclusion: Conformity.				

2 days at 55°C-30th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:44,6" Conclusion: Conformity.				

2 days at 55°C-60th day

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+

	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:45,2" Conclusion: Conformity.				

2 days at 55°C-Month 6

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:46,3" Conclusion: Conformity.				

2 days at 55°C-Month 12

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-

	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:46,9" Conclusion: Conformity.				

2 days at 55°C-Month 18

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027	-	-
	N1B	CN027	-	-
	N2A	CN027	-	-
	N2B	CN027	-	-
	N3A	CN027	-	-
	N3B	CN027	-	-
	N4A	CN027	-	-
	N4B	CN027	-	-
	N5A	CN027	-	-
	N5B	CN027	-	-
Positive Reference panel	A1A	CN085	+	+
	A1B	CN085	+	+
	A2A	CN085	+	+
	A2B	CN085	+	+
	A3A	CN085	+	+
	A3B	CN085	+	+
	A4A	CN085	+	+
	A4B	CN085	+	+
	A5A	CN085	+	+
	A5B	CN085	+	+
C line appearing time:≤60", T line density:47,6" Conclusion: Conformity.				

2 days at 55°C-Month 21

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		

	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density: Conclusion: Studies continue.				

2 days at 55°C-Month 24

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density: Conclusion: Studies continue.				

2 days at 55°C-Month 25

Reference Panel	LOT	LOT:CN2105N01	LOT:CN2105N02

Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density: Conclusion: Studies continue.				

2 days at 55°C-Month 27

Reference Panel		LOT	LOT:CN2105N01	LOT:CN2105N02
Negative Reference panel	N1A	CN027		
	N1B	CN027		
	N2A	CN027		
	N2B	CN027		
	N3A	CN027		
	N3B	CN027		
	N4A	CN027		
	N4B	CN027		
	N5A	CN027		
	N5B	CN027		
Positive Reference panel	A1A	CN085		
	A1B	CN085		
	A2A	CN085		
	A2B	CN085		
	A3A	CN085		
	A3B	CN085		
	A4A	CN085		
	A4B	CN085		
	A5A	CN085		
	A5B	CN085		
C line appearing time: T line density:				

Conclusion: Studies continue.

8. Conclusion

We will conduct the study according to the above plan.

REGULATORY & QUALITY

APPLICABLE STANDARDS

Document No	Document Name
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 9001	Quality management systems - Requirements
EN 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13612	Performance evaluation of in vitro diagnostic medical devices
ISO 15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
-	Nasopharyngeal antigen detection for SARS-CoV-2 Performance evaluation of a lateral flow assay for diagnosis
-	COVID-19: Rapid Antigen detection f 1 or SARS-CoV-2 by lateral flow 2 assay: a national systematic evaluation for mass-testing
ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 14791	Medical devices — Application of risk management to medical devices
EN ISO 17511	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)
ISO 23640	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
ISO 18113-1	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
ISO 18113-2	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
ISO 18113-3	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use
ISO 18113-4	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing

ISO 18113-5	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing
2017/746	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

CE AT UYGUNLUK BEYANI

EU DECLARATION OF CONFORMITY

ÜRETİCİ **MANUFACTURER**	:	CESNA BİYOTEKNOLOJİ ARAŞTIRMA GELİŞTİRME LABORATUVAR SİST. İNŞ. MÜH.DAN. SAN. TİC.LTD. ŞTİ.
ADRES **ADRESS**	:	Ramazanoğlu Mah.Karşıgeçit Sok.No:5/42 Pendik/İstanbul

Aşağıda tanımlanmış olan ürünler için In Vitro Diagnostik Tıbbi Cihaz Direktifi 98/79/EC uyarınca, gerekliliklerinin yerine getirildiğini ve sorumluluğun alınmış olduğunu beyan ederiz.

In accordance with the in Vitro Diagnostic Medical Device Directive 98/79/EC for the products described below, we declare that their requirements have been done and we take the responsibility.

ÜRÜN **PRODUCT**	:	Check Up SARS-CoV-2 Nasal Antigen Rapid Test
MODEL **TYPE**	:	Check Up SARS-CoV-2 Nasal Antigen Rapid Test
HARMONISED STANDARTS:	:	ISO 9001 ISO 13485 Bu uygunluk beyanı üreticinin münhasır sorumluluğu altında sunulmuştur. This declaration of conformity is issued under the exclusive responsibility of the manufacturer.

Place of issue Istanbul
Date issue February 10, 2021

Engin NARİNÇ

Manager

CESNA BİYOTEKNOLOJİ
ARAŞTIRMA GELİŞTİRME LABORATUVAR
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Ramazanoğlu Mh. Karşıgeçit Sk. No:5/42 Pendik-İST.
Pendik V.D. - 206 068 7154

INSTRUCTION FOR USE

CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST

REF **C2104N01** CE

For professional use only. For only in vitro diagnostic use.

PACKAGING UNITS

1T/Set,5T/Set,10T/Set,25T/Set,40T/Set,50T/Set

INTENDED USE

This kit is used for in vitro qualitative detection of SARS-CoV-2 antigen. It is a lateral flow immunoassay designed for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 directly in the nose.

This test is for clinical laboratory use only or for emergency examination by medical personnel, is not home tested and cannot and is not intended to be used as a basis for diagnosing and excluding pneumonia caused by a recent Covid-19 infection. general population. A positive test result should be further confirmed. A negative test result cannot rule out an infection. The kit and test results are for clinical reference only. It is recommended to combine the patient's clinical findings and other laboratory tests for a comprehensive analysis of the condition.

SUMMARY

The novel coronaviruses belong to the genus ß. SARS-CoV-2 is an acute infectious disease of the respiratory tract. People tend to be vulnerable. Currently, patients infected with the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source.

Based on the current epidemiological investigation, the incubation period is 1 to 14 days, usually 3 to 7 days. The main manifestations are fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in some cases.

PRINCIPLE

This reagent uses a lateral flow immunoassay to legally detect the antigen of the new coronavirus (SARS-CoV-2) in nasal swab samples.

During detection, the gold-marked anti-SARS-CoV-2 monoclonal antibody in the marking pad binds to the SARS-CoV-2 antigen in the sample to form a complex and the reaction complex moves forward across the nitrocellulose membrane. It is captured by the anti-SARS-CoV-2 monoclonal antibody pre-coated with the detection zone (T) on the chromatography membrane and finally a red colored reaction line is formed in the T zone. The SARS-CoV-2 antigen cannot create a red colored reaction line in the T region. Regardless of whether the sample to be tested contains the SARS-CoV-2 antigen or not, a red reaction line will always appear in the quality control area (C).

MATERIALS AND COMPONENTS

Materials supplied with test kits

1.Test cassette

2.Sterile swabs

3.Sample buffer

4.Instructions for use

***Note:** The components in different batches cannot be mixed.

Materials required but not provided

- Personal protective equipment
- Transfer pipette
- Timer

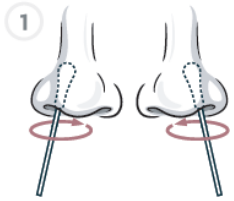
STORAGE AND STABILITY

1. Store at 2°C-30°C in a sealed bag until the expiry date printed on the package. Store in a bar, store below 2°C and avoid using expired products.
2. The test card is used within 15 minutes after it is removed from the foil envelope. The buffer solution is limited to a suitable time after use.
3. The pad should be used immediately after insertion into the dropper.
4. Do not freeze.
5. Do not use after expiry date.

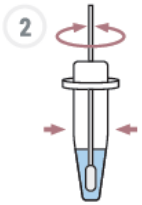
INSTRUCTIONS FOR IMPLEMENTATION

Before starting the test, read the instruction manual and carefully follow the 12 steps below.

1. Carefully insert the entire soft tip of the swab about an inch deep into your nostril.
2. Using a little pressure, rub the swab in as slowly as possible a circular motion around the inside wall of your nose for 5-7 times 15 seconds.
3. Please repeat the same procedure with the same smear in the other nostril.



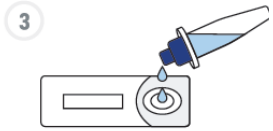
4. Place the swab in the tube with the extraction solution.
Break the swab at the break and close the cap of the tube so that it remains inside the swab.
5. At least 15 seconds mix the tube.



6.Pack the used swab in the enclosed plastic bag for contaminated waste.

7. If the test cassette has not been stored at room temperature (10° C to 30 °C) they should be stored at room temperature for 15 to 30 minutes.

8. Put exactly 2 drops from the collection tube into the sample hole of the test cassette. The sample/conjugate complex will migrate towards the nitrocellulose membrane. If no movement is seen in the membrane, put 3 drops into the sample hole of the test cassette.



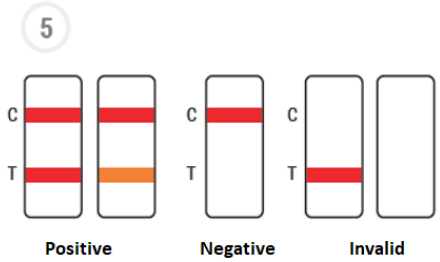
9. (At an ambient temperature of 10 ° C to 30 ° C) You can read the result on the test cassette after 15 minutes. Results that are displayed on the test cassette after 30 minutes are invalid.

10. Read the results according to the following.

11. After testing, place all components of this test in a sealed plastic bag for contaminated waste and seal this bag with any remaining waste. Cannot be reused.

12. Wash or disinfect hands again

INTERPRETATION OF TEST RESULTS



This product is used for qualitative determination only.

Positive result: If both C and T lines are visible within 15 minutes, the test result is positive and valid.

* Note: Samples with very low target levels of antibodies may develop two lines of color over 15 minutes.

Negative result: If the test area (T-line) has no color and the control area shows a colored line, the result is negative and valid.

Invalid result: The test result is invalid if there is no colored line in the control area. The sample must be retested with a new test cassette.

RESTRICTIONS

1. The product result should not be taken as a confirmed diagnosis for clinical reference only. The decision should be made in conjunction with RT-PCR results, clinical symptoms, epidemiological information, and other clinical data.
2. The contents of this kit are extracted from nasal swab samples for the qualitative detection of SARS-CoV-2 antigens.
3. This test detects both live (live) and non-viable SARS-CoV-2 and SARS-CoV-2. Test performance is dependent on the amount of virus (antigen) in the sample and may correlate with virus culture results performed on the same sample.
4. The sample buffer and test card must be equilibrated to room temperature (18 °C to 26 °C) before use, otherwise results may be inaccurate.
5.A negative test result may occur if the antigen content in a sample is below the detection limit of the assay or if the sample was improperly removed or transported.
6. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
7. Responding earlier than 15 minutes may result in a false negative result; If you react after 15 minutes, this can lead to a false positive result.
8. Positive test results do not exclude the possibility of co-infection with other pathogens.
9. Positive test results do not distinguish between SARS-CoV and SARS-CoV-2.
10. Negative test results are not intended to respond to other non-SARS virus or bacterial infections.

11. Clinical performance has been evaluated on frozen specimens and performance may vary in fresh specimens.

12. Users should test samples as soon as possible after sample collection.

13. Chromatography cannot be successfully performed if the sample volume is insufficient. Please pay attention to the quick information of the device. It is recommended to use a pipette to add samples.

13. Chromatography cannot be successfully performed if the sample volume is insufficient. Please pay attention to the quick information of the device. It is recommended to use a pipette to add the sample.

PERFORMANCE CHARACTERISTICS

1. Clinical review

The SARS Cov-2 Rapid Test Kit was administered on 299 nasal swabs collected from symptomatic patients who developed symptoms within 7 days. A limited number of patients with symptoms for more than 7 days and asymptomatic patients were included in the clinical study (n = 304). The sample size was relatively significant, with 99.3% positive agreement (302/304) and 98.8% negative agreement (445/450). The test is designed for professional use.

	Comparative RT-PCR test resu		
	Positive	Negative	**Total**
Positive	302	5	307
Negative	2	445	447
Total	304	450	754
Sensitivity: 302/304 99,3 %, (95% CI: 95.82,98.51)			
Specificity: 445/450 98,8%, (95% CI:97.81, 99.69)			

2. Detection limit

At a virus culture concentration of 100 TCID50/ml and higher, the positive rate was greater than or equal to 95%. With a virus culture concentration of 50 TCID50/ml and below, the positive rate is no higher than 95%, so the minimum detection limit of the S Check Up SARS-CoV-2 Nasal Antigen Rapid Test is 100 $TCID_{50}$/ml.

3. Cross reactivity

The cross-reactivity of the kit was assessed. The results showed no cross-reactivity with the following examples.

Nu.	Specimen type	Result
1	HCoV-HKU1	10^5 TCDI $_{50}$/ml
2	Staphylococcus aureus	10^6 CFU /ml
3	Streptococcus pyogenes	10^6 CFU / ml
4	Measles virus	10^5 $TCID_{50}$/ ml
5	Paramyxovirus parotitis	10^5 TCID $_{50}$/ ml
6	Adenovirus 3	10^5 $TCID_{50}$ / ml
7	Mycoplasma pneumonia	10^6 CFU_{50} / ml
8	Parainfluenza virus 2	10^5 $TCID_{50}$ /ml
9	Human Metapneumovirus (Hmpv)	10^5TCID_{50}/ ml
10	Human coronavirus OC43	10^5 $TCID_{50}$ /ml
11	Human coronavirus NL63	10^5 TCID $_{50}$/ml
12	Human coronavirus 229E	10^5 $TCID_{50}$/ml
13	MERS Coronavirus	10^5 $TCID_{50}$/ml
14	Bordetella parapertussia	10^5 $TCID_{50}$/ml
15	Influenza B (Victoria strain)	10^5 $TCID_{50}$/ml
16	Influenza B (Ystrain)	10^5 $TCID_{50}$/ml
17	Influenza A (H1N1 2009)	10^5 $TCID_{50}$/ml
18	Influenza A (H3N2)	10^5 $TCID_{50}$/ml
19	Avian influenza virus (H7N9)	10^5 $TCID_{50}$/ml
20	Avian influenza virus (H5N1)	10^5 $TCID_{50}$/ml
21	Epstein-Barr virus	10^5 $TCID_{50}$/ml
22	Enterovirus CA16	10^5 $TCID_{50}$/ml
23	Rhinovirus	10^5 $TCID_{50}$/ml
24	Respiratory syncytial virus (RSV)	10^5 $TCID_{50}$/ml
25	Streptococcus pneumoniae	10^6 CFU / ml
26	Candida albicans	10^6 CFU / ml
27	Chlamydia pneumoniae	10^6 CFU / ml
28	Bordetella pertussis	10^6 CFU / ml
29	Pneumocystis jirovecii	10^6 CFU / ml
30	Mycobacterium tuberculosis	10^6 CFU / ml
31	Legionella pneumophila	10^6 CFU / ml

1. Interference substances

The test results are not affected with the substance at the following concentration.

Nu.	Contaminants	Result
1	Whole Blood	4%
2	Ibuprofen	1 mg / ml
3	Tetracycline	3µg / ml
4	Chloramphenicol	3µg / ml
5	Erythromycin	3µg / ml
6	Tobramycin	5%
7	Throat spray（Menthol）	15%
8	Mupirocin	10mg/ml
9	Throat lozenge（Menthol）	1.5mg/ml
10	Tamiflu (Oseltamivir)	5mg/ml
11	Naphthoxoline Hydrochloride nasal drops	15%
12	Mucin	0.50%
13	Fisherman's Friend	1.5mg/ml
14	Compound Benzocain Gel	1.5mg/ml
15	Cromoglycate	15%
16	Sinex (Phenylephrine Hydrochloride)	15%
17	Afrin (Oxymetazoline)	15%

18	Fluticasone propionate spray	15%

2. Precision

10 replicates of negative and positive samples were tested using company reference materials. Negative agreement and positive agreement were 100%. Try three different loose-fitting kits, including positive and negative company reference materials. Negative outcomes and positive outcomes were 100%.

5. Hook effect

No hook effect was observed when the concentration of the inactivated virus stock increased to 4.0 × 105 TCID50/ml.

PRECAUTIONS

1. Do not use the contents of the kit beyond the expiration date printed on the outside of the package.
2. Take appropriate precautions in sampling, handling, storage and disposal of the product.
3. Do not reuse used materials.
4. Do not remove the test card from its packaging until you use it.
5. Do not use damaged tests.
6. If the reagent solution comes into contact with the skin or eyes, rinse with plenty of water.
7. Inadequate or improper specimen collection, storage, and transport may lead to inaccurate test results.
8. Sample collection and handling procedures require specific training and guidance.
9. Use the appropriate fixed-volume pipette according to the test procedures.
10. The test should be performed in an area with adequate ventilation.
11. Wear suitable protective clothing, gloves, and eye / face protection when handling the contents of this kit.
12. Wash hands thoroughly after handling.

LIST OF SYMBOLS

	Manufacturer
IVD	In vitro Diagnostics medical device
	Consult the operating instructions
EC REP	Authorized representative in the European Community
	Best before date
LOT	Batch code
	Temperature limit
	Do not use multiple times
REF	Catalog number
	manufacturing date
CE	CE marking
	Keep dry
	Attention
	Do not use if the package is damaged
	Protect from sunlight

CONTACT

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E-Mail: info@cesna.com.tr
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ESSENTIAL REQUIREMENTS

General Requirements

1.		Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
2.		The requirements in this annex to reduce risks as far as possible mean reduce risks as far as possible without adversely affecting the risk benefit ratio.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
3.		The manufacturer shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:				
	a)	establish and document a risk management plan for each device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	identify and analyse the known and foreseeable hazards associated with each device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	c)	estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

	d)	eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	e)	evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	f)	based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
4.		Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:				
	a)	eliminate or reduce risks as far as possible through safe design and manufacture;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	c)	provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
		Manufacturers shall inform users of any residual risks.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

5.		In eliminating or reducing risks related to use error, the manufacturer shall:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	a)	reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
6.		The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
7.		Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
8.		All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
9.		For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

II	**Requirements regarding design and manufacture**					
10.	Chemical, physical and biological properties					
10.1		Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:				
	a)	the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	c)	the compatibility between the different parts of a device which consists of more than one implantable part;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	d)	the impact of processes on material properties;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	e)	where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	f)	the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	g)	surface properties; and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
		the confirmation that the device meets any defined chemical and/or physical specifications.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

10.2		Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.3		Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.4	Substances					
10.4.1		**Design and manufacture of devices** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	-	are invasive and come into direct contact with the human body,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	-	(re)administer medicines, body liquids or other substances, including gases, to/from the body, or	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

	-	transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
		shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	a)	substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council2 or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council3, in accordance with the criteria that are relevant to human health amongst the criteria established therein.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.4.2		Justification regarding the presence of CMR and/or endocrine-disrupting substances The justification for the presence of such substances shall be based upon:				
	a)	an analysis and estimation of potential patient or user exposure to the substance;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

	c)	argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	d)	where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.4.3		*Guidelines on phthalates* For the purposes of Section 10.4., the Commission shall, as soon as possible and by … [one year after the date of entry into force of this Regulation], provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before … [date of application of this Regulation]. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.4.4		*Guidelines on other CMR and endocrine-disrupting substances* Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

		Labelling Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.5		Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
10.6		Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.	Infection and microbial contamination					
11.1		Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	a)	reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	allow easy and safe handling,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

	c)	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	d)	prevent microbial contamination of the device or its content such as specimens or fluids.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.2		Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.3		Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.4		Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.5		Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.6		Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
11.7		Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

11.8		The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
12.	Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.					
12.1		In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.				
12.2		Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.				
13.	Devices incorporating materials of biological origin					
13.1		For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:				
	a)	donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

	b)	processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	c)	the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
13.2	For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:					
	a)	where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;				
	b)	sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;				
	c)	in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.				

13.3		For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.				
14.	Construction of devices and interaction with their environment					
14.1		If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
14.2		Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:				
	a)	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	c)	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

	d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	e)	the risks of accidental ingress of substances into the device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	f)	the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
	g)	risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
14.3		Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
14.4		Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
14.5		Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
14.6		Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

14.7		Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
15.	Devices with a diagnostic or measuring function					
15.1		Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
15.2		The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC1.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
16.	Protection against radiation					
16.1		General				
	a)	Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.				
	b)	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.				
16.2		Intended radiation				

	a)	Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.				
	b)	Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.				
16.3		Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.				
16.4		Ionising radiation				
	a)	Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.				
	b)	Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment.				
	c)	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.				

	d)	Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.				
17.	Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves					
17.1		Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.				
17.2		For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.				
17.3		Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).				
17.4		Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.				
18.	Active devices and devices connected to them					
18.1		For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.				

18.2		Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.				
18.3		Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.				
18.4		Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.				
18.5		Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.				
18.6		Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.				
18.7		Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.				
18.8		Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.				
19.	Particular requirements for active implantable devices					
19.1		Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:				

	a)	risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,				
	b)	risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and				
	c)	risks which may arise where maintenance and calibration are impossible, including:				
	-	excessive increase of leakage currents,				
	-	ageing of the materials used,				
	-	excess heat generated by the device,				
	-	decreased accuracy of any measuring or control mechanism.				
19.2		Active implantable devices shall be designed and manufactured in such a way as to ensure				
	-	if applicable, the compatibility of the devices with the substances they are intended to administer, and				
	-	the reliability of the source of energy.				
19.3		Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.				
19.4		Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.				
20.	Protection against mechanical and thermal risks					
20.1		Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports

20.2		Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
20.3		Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
20.4		Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
20.5		Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
20.6		Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports
21.	Protection against the risks posed to the patient or user by devices supplying energy or substances					
21.1		Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.				

21.2		Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.				
21.3		The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.				
22	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons					
22.1		Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
22.2		Devices for use by lay persons shall be designed and manufactured in such a way as to:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
	-	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
	-	reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website

	-	reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
22.3		Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
	-	can verify that, at the time of use, the device will perform as intended by the manufacturer, and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
	-	if applicable, is warned if the device has failed to provide a valid result.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	EN 13641, ISO 14971, ISO 10993-1, ISO 13485	Risk management procedure,Risk management reports, Instruction for use, video for lay people on the website
Chapter III	**Requirements regarding the information supplied with the device**					
23.	Label and instructions for use					
23.1		General requirements regarding the information supplied by the manufacturer				
		Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:				

	a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
	b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
	c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
	d)	Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
	e)	Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
	f)	Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
	g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com

	h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, video for lay people on the website,www.visionbiotechnology.com
23.2		Information on the label				
		The label shall bear all of the following particulars:				
	a)	the name or trade name of the device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	b)	the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	d)	if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	e)	where applicable, an indication that the device contains or incorporates:				
	-	a medicinal substance, including a human blood or plasma derivative, or				
	-	tissues or cells, or their derivatives, of human origin, or				
	-	tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;				

	f)	where applicable, information labelled in accordance with Section 10.4.5.;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	g)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	h)	the UDI carrier referred to in Article 27(4) and Part C of Annex VII;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	i)	an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	j)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	k)	an indication of any special storage and/or handling condition that applies;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	l)	if the device is supplied sterile, an indication of its sterile state and the sterilisation method;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design

	m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	n)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	o)	if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	p)	if the device is custom-made, the words 'custom-made device';	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	q)	an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	r)	in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design
	s)	for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	packing procedure,package design

23.3		Information on the packaging which maintains the sterile condition of a device ('sterile packaging')				
		The following particulars shall appear on the sterile packaging:				
	a)	an indication permitting the sterile packaging to be recognised as such,				
	b)	a declaration that the device is in a sterile condition,				
	c)	the method of sterilisation,				
	d)	the name and address of the manufacturer,				
	e)	a description of the device,				
	f)	if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',				
	g)	if the device is custom-made, the words 'custom-made device',				
	h)	the month and year of manufacture,				
	i)	an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and				
	j)	an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.				
23.4		Information in the instructions for use				
		The instructions for use shall contain all of the following particulars:				

	a)	the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	b)	the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	c)	where applicable, a specification of the clinical benefits to be expected.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	d)	where applicable, links to the summary of safety and clinical performance referred to in Article 32;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	e)	the performance characteristics of the device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	f)	where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	g)	any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	h)	specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

	i)	details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	j)	any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	k)	the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	identification of any consumable components and how to replace them,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

	l)	if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	m)	if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	n)	if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	o)	an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	p)	if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	q)	for devices intended for use together with other devices and/or general purpose equipment:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

	-	information to identify such devices or equipment, in order to obtain a safe combination, and/or	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	information on any known restrictions to combinations of devices and equipment;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	r)	if the device emits radiation for medical purposes:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	the means of protecting the patient, user, or other person from unintended radiation during use of the device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	s)	information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

	-	warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
		precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	t)	in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

	u)	in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	v)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	-	physical hazards such as from sharps.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
		If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	w)	for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	x)	for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	y)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

	z)	a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	aa)	information to be supplied to the patient with an implanted device in accordance with Article 18;	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com
	ab)	for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	Yes	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	EN 13641, ISO 14971, ISO 10993-1, ISO 13485,ISO 23640,ISO 18113-4,ISO 15223-1	Instruction for use, website,www.visionbiotechnology.com

Material Safety Data Sheet

（MSDS）

1 Identification of the substance / preparation and the company	
Product name	CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST
Cat No	C2104N01
Molecular formula	N/A
Identification company	Ramazanoğlu Mah.Karşıgeçit Sok.No:5/42 Pendik/Istanbul 0216 784 02 98 www.cesnalaboratuvarsistemleri.com Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist. İnş.Müh.Dan.San.Tic.Ltd.Şti.
Intended use	In Vitro Diagnostics

2 Hazards identification	
Hazard designation	N/A
Invasive approach	Ingestion and contact
Health hazards	According to the documentation available is not a hazardous substance/preparation within the meaning of the EEC directive 67/548 and 99/45. The usual hygienic measures taken when handling biological materials should be observed. See Section 11 Toxicological Information for more detailed health information.
Enviromental hazards	Slightly hazardous to water and ground
Explosive hazards	N/A

3 Composition / information on ingredients		
Unmixture/mixture	Mixture	
Ingredient	R1： Sample buffer R2： Anti-NP mAb antibody	
Appearance	Liquid	
Hazards ingredients		
Name	**Concentration**	**CAS No.**
N/A	N/A	N/A

4 First-aid measures	
Skin contact	Wash immediately with plenty of water and treat the contacted skin with skin-disinfectant.
Eye contact	Promptly wash eyes with water for at least 15 minutes, seek medical advice.
Inhalation	If breathing becomes difficult, remove victim to fresh air. Seek medical assistance immediately.
Ingestion	If accidentally swallowed obtain immediate medical attention.
Medical treatment	Symptomatic treatment by a physician.
5 Fire-fighting measures	
Dangerous Properties	Liquid is not inflammable.
Hamful product of burned	N/A
Suitable extinguishing method	Carbon dioxide (CO2), extinguishing powder or water spray/fog. Fight larger fires with water spray/fog or alcohol-resistant foam.
Notes	Collect contaminated fire fighting water separately. It must not enter drains.
6 Accidental release measures	
Personal precautions	Wear gloves and laboratory coat. Prevent skin and eye contacting.
Environmental precautions	Keeping away from drains, surface- and ground-water and soil.
Methods for cleaning up	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to item 13.
7 Handling and storage	
Information for safe handling	Ensure good ventilation/exhaustion at the workplace. Do not inhale aerosols. Avoid prolonged or repeated skin contact. Avoid contact with eyes. Make sure that all applicable workplace limits are observed.
Information for safe Storage	Keep packge tightly sealed. Protect from heat and direct sunlight. Store in a cool place. Recommended storage temperature: 2 - 8 °C.
8 Exposure controls / personal protection	
Concentration limits	N/A

Protective equipment	Keep away from foodstuffs, beverages and food. Do not inhale gases / fumes / aerosols. Avoid close or long term contact with the skin. Avoid contact with the eyes. Wash hands during breaks and at the end of the work.
Respiratory protection	Surgical mask
Eye protection	Safety glasses
Body protection	Light weight protective clothing, such as surgical clothes.,
Hand protection	Protective gloves ,The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Other protection	Prevent the product from entering drains and watercourses.

9 Physico-chemical properties	
Appearance	Liquid
pH	R1：7.80±0.50；R2：7.50±0.50
Melting point	N/A
Boiling point	N/A
Relative density	N/A
Vapour pressure	N/A
Vapour density	N/A
Partition coefficient	N/A
Flash point (typical)	N/A
Autoignition temperature	N/A
Decompose temperature	N/A
Burnning/explosion limits(Upper)	N/A
Burnning/explosion limits(lower)	N/A
Miscibility with water	N/A

10 Stability and reactivity	
Stability	Stable under normal conditions of use.
Conditions to avoid	High temperature , light
Materials to avoid	Strong oxidizing agents、Strong acids 、Heavy metals
Hazardous decomposition products	Bottle and package 、Gloves and laboratory coat and others

11 Toxicological information	
Acute toxicity	N/A
Skin contact	No irritant effect.
Eye contact	No irritant effect.
Inhalation/Sensitization	No irritant effect.
Germ cell mutagenicity	N/A
Carcinogenicity	N/A
Reproductive toxicity	N/A
Specific target cells in systemic toxicity - throwaway contact	N/A
Specific target cells in systemic toxicity - repeated contact	N/A
Ingestion	Unknown

12 Ecological information	
Ecotoxicity	N/A
Persistence/degradability	N/A
Bioaccumulation potential	N/A
Mobility in soil	N/A

13 Disposal considerations	
Properties	Biological hazard
Disposal method	Waste disposal route: Used reagent can be disposed of in the waste water in accordance with local regulations. Disposal of empty packaging: Dispose of empty packs via local recycling or waste disposal routes if necessary, clean them beforehand.

14 Transport information	
Dangerous goods number	N/A
UN code	N/A
Hazard Classification	N/A
Marine pollution	N/A
Package symbol	N/A
Package classification	N/A

Package method	Put sealed bottle in internal narrow lane,and seal the package. Put the package in EPS container with ice bag,and fit it in carton for transport.
Transport / further information	This substance is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15 Regulations

The product has not to be classified and labelled in accordance with EC Directives / relevant national laws.

16 Other information

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our product is responsible for ensuring that, where applicable, existing laws and guidelines are observed.

Special permission has been granted in accordance with EU Directive 99/45, Article 9, which permit small packages of up to 125 ml or 125 g containing materials that are harmful to health or irritant to be unlabelled with the hazard identification information given in the safety data sheet.

Notes:The “N/A”is means “Not available”.

Product

1T/Set:

25T/Set:

CERTIFICATE

CESNA BİYOTEKNOLOJİ ARAŞ. GELİŞ. LABORAT. SİST. İNŞ. MÜH. DANŞ. SAN. TİC. LTD.ŞTİ
RAMAZANOĞLU MAH. KARŞIGEÇİT SK. NO:5 İÇ KAPI NO:42 PENDİK/ İSTANBUL

Kapsam: "BİYOTEKNOLOJİYLE İLGİLİ ARAŞTIRMA VE DENEYSEL GELİŞTİRME FALİYETLERİ TIBBİ CİHAZLARIN ÜRETİMİ VE SATIŞI, DIŞ TİCARET, YÖNTEM VE İDARİ ORGANİZASYON FAALİYETLRİ İLE BU FAALİYETLERLE İLİŞKİLİ İŞLEMLERİNİVE BUNLARA BAĞLI HİZME SUNUMLARI

For: "RESEARCH AND EXPERIMENTAL DEVELOPMENT ACTIVITIES RELATED TO BIOTECHNOLOGY, MANUFACTURING AND SALES OF MEDICAL DEVICES, FOREIGN TRADE, METHOD AND ADMINISTRATIVE ORGANIZATION ACTIVITIES, AND THE ACTIVITIES RELATED TO THESE ACTIVITIES"

TS EN ISO 13485 : 2016
TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ
(MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM)

Kurduğunu Ve Uyguladığını Belgelemekte Ve EKOL Tarafından Gerçekleştirilen Denetim Bu yönetim Sisteminin Yukarıda Belirtilen Standardın Şartlarını Karşıladığını Doğrulamaktadır.

It Certifies That İt İs Established And İmplemented, And The Audit Performed By EKOL İt Confirms That This Management System Meets The Requirements Of The Following Standard.

Sertifika Numarası / *Certificate Number*	**: 9101925064**
Sertifika Kodu / *Certificate Code*	**: CESNA**
Sertifika Yayın Tarihi / *Certificate Issue Date*	**: 08.09.2021**
Sertifika Geçerlilik Tarihi / *Certificate Validity Date*	**: 08.09.2022**
Sertifika Periyodu / *Certificate Period*	**: 1 Yıl / *1 Year***

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Belge Değerlendirme Müdürü

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Belgenin geçerlilik durumu **https://www.ekolbelgelendirme.com/sertifikaara/** adresinden kontrol edilebilir.