Test report

On Behalf of

[redacted] Trade Secret / proprietary knowledge

Disposable Medical Mask

Model :KX45881,

KX45882, KX45883,

KK45880, KK45881

Prepared For : [redacted] Trade Secret / proprietary knowledge

Prepared By : **China Ceprei (Sichuan) Laboratory**
No.45 Wenming Dong Road Longquanyi District, Chengdu, Sichuan

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MDD REPORT

EN 14683

Surgical masks - Requirements and test methods

EN ISO 14971

Application of risk management to medical devices

EN 1041

Information supplied by the manufacturer of medical devices

EN ISO 10993

Biological evaluation of medical devices

Part 1: Evaluation and testing

EN ISO 15223

Medical devices —

Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Test by ..... :	China Ceprei (Sichuan) Laboratory
Address .....:	No.45 Wenming Dong Road Longquanyi District, Chengdu, Sichuan
Report body.....:	China Ceprei (Sichuan) Laboratory
Address ..... :	No.45 Wenming Dong Road Longquanyi District, Chengdu, Sichuan
Applicant ..... :	
Address .....:	
Standard ..... :	EN 14683:2019+AC:2019,EN ISO 14971:2012, EN ISO 15223-1:2016, EN1041:2008, EN ISO 10993-1:2009/AC:2010
Test Result ..... :	Compliance with EN 14683:2019+AC:2019, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010
Procedure deviation ..... :	N.A.
Non-standard test method .....:	N.A.
Type of test object ..... :	Disposable Medical Mask
Trademark ..... :	Nugar
Model/type reference ..... :	KX45881, KX45882, KX45883, KK45880, KK45881
Rating .....:	--
Manufacturer ..... :	[redacted] Trade Secret / proprietary knowledge
Address ..... :	

General remarks

This report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item(s) tested.

"(see appended table)" refers to a table appended to the report.

“(see remark #)” refers to a remark appended to the report.

“(see Annex #) refers to an annex appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

Sample photo:

(See appendix 1-2)

Marking label:

(See appendix 3)

Possible test case verdicts :	
test case does not apply to the test object …….. :	N(.A.)
test object does meet the requirement …….. :	P(ass)
test object does not meet the requirement …….. :	F(ail)

Test by :China Ceprei (Sichuan) Laboratory
No.45 Wenming Dong Road Longquanyi District, Chengdu, Sichuan

Reported by : Anna Deng
Signature / Jack Deng / Engineer — Date: Mar.11,2020

Checked by : Gina Zhong
Signature / Gina Zhong / Engineer — Date: Mar.11,2020

Approved by : Martin Wang
Signature / Jakson Zhang / Manager — Date: Mar,11,2020

EN 14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
1	Scope		P
2	Normative references		P
3	Terms and definitions		P
3.1	medical face mask medical device covering the mouth and nose providing a barrier to minimise the direct transmission of infective agents between staff and patient		P
3.2	bacterial filtration efficiency (BFE) efficiency of the medical face mask material(s) as a barrier to bacterial penetration Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.		P
3.3	differential pressure air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity		P
3.4	colony forming unit (cfu) unit by which the culturable number of micro-organisms is expressed Note 1 to entry: The culturable number is the number of micro-organisms, single cells or aggregates, able to form colonies on a solid nutrient medium.		P
3.5	cleanliness freedom from unwanted foreign matter		P
3.5.1	cleanliness — microbial freedom from population of viable micro-organisms on a product and/or a package		P
3.5.2	cleanliness — particulate matter freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact		P
3.6	infective agent micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other		P
3.7	surgical procedure surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions		P
3.8	aerosol gaseous suspension of solid and/or liquid particles, the particles having a negligible falling velocity Note 1 to entry: See EN 132. Note 2 to entry: This velocity is generally considered to be less than 0,25 m/s.		P
3.9	filter material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled		P

EN 14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	and exhaled air		
3.10	splash resistance ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure		P
	4 Classification Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.	Type I	P
5	Requirements		P
5.1	General		P
	5.1.1 Materials and construction The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness	absence of particulate matter	P
5.1.2	Design The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours)	Metal strip fixing	P
5.2	Performance requirements		P
5.2.1	General All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.		P
5.2.2	Bacterial filtration efficiency (BFE)	Bacterial filtration	P
	When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	efficiency (BFE), (%) ≥ 95% Differential pressure (Pa/cm2) < 29.4 Microbial cleanliness (cfu/g) ≤ 30	P
5.2.3	Breathability When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.		P
5.2.4	Splash resistance When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		P
5.2.5	Microbial cleanliness (Bioburden) When tested according to EN ISO 11737-1 the		P

EN 14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1). NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package. To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below: The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.		
5.2.6	Biocompatibility According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request. As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P
6	Labelling and information to be supplied		P
	The following information shall be supplied in addition: a) number of this European Standard; b) type of mask (as indicated in Table 1).		P
Annex A	Information for users		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
Annex B	Method for in-vitro determination of bacterial filtration efficiency (BFE)		P

Test data

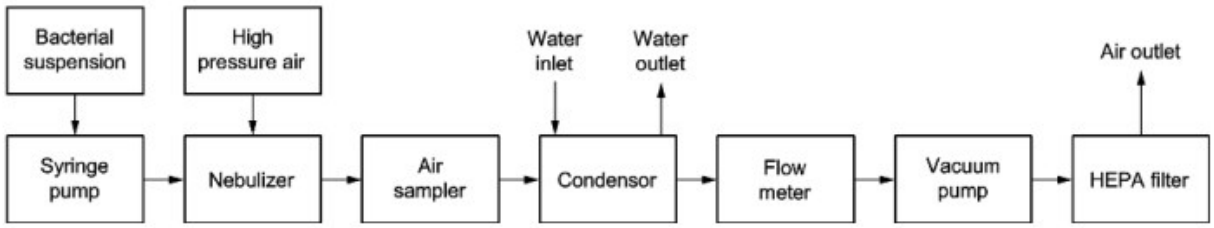
Ambient temperature: 24 ℃ Relative Humidity (RH): 32%					
Sample	Items	Limits(%)	Initial filtration efficiency(%)	Loading filter efficiency(%)	Conclusion
Non- temperature conditioning samples					
#1	Filtration Efficiency	Test gas flo w single filter element 085 ± 4) l / min >80	95.3	95.2	PASS
#2			95.2	95.2	PASS
#3			95.3	95.3	PASS
#4			95.2	95.1	PASS
#5			95.3	95.2	PASS
#6			95.3	95.2	PASS
Temperature conditioning samples					
#7	Filtration Efficiency	Test gas flo w single filter element 0 95 ± 4) l / min >80	95.3	95.3	PASS
#8			95.2	95.1	PASS
#9			95.3	95.2	PASS
#10			95.3	95.2	PASS
Sample	Items	Limits(%)	Data （Pa）		Conclusion
Non- temperature conditioning samples					
#11	Inspiratory resistance	The total gas resistance of each sample should be ≤ 350Pa	141		PASS
#12			141		PASS
#13			142		PASS
#14			145		PASS
#15			141		PASS
#16			144		PASS

Temperature conditioning samples				
#17	Inspiratory resistance	The total gas resistance of each sample should be ≤	152	PASS
#18			154	PASS
#19			158	PASS

Documentation

#20		350Pa	156	PASS
#21			157	PASS
Non- temperature conditioning samples				
#22	Expiratory resistance	The total gas resistance of each sample should be ≤ 250Pa	65	PASS
#23			68	PASS
#24			85	PASS
#25			65	PASS
#26			65	PASS
#27			65	PASS
Temperature conditioning samples				
#28	Expiratory resistance	The total gas resistance of each sample should be ≤ 250Pa	92	PASS
#29			91	PASS
#30			89	PASS
#31			92	PASS
#32			93	PASS
#33			91	PASS
#34			90	PASS
Note:		Temperature conditions a) 24 hours at 38 ℃ and 85% b) At 70 ℃ for 24 hours c) 24 hours at -30 ℃		

Principle of BFE test apparatus



EN ISO 14971			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
3	General requirements for risk management		P
3.1	Risk management process		P
3.2	Management responsibilities		P
	Top management shall provide evidence of its commitment to the risk management process by: ensuring the provision of adequate resources and ensuring the assignment of qualified personnel (see 3.3) for risk management		P
3.3	Qualification of personnel		P
	Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. These shall include, where appropriate, knowledge and experience of the particular medical device (or similar medical devices) and its use, the technologies involved or risk management techniques. Appropriate qualification records shall be maintained.		P
3.4	Risk management plan		P
	Risk management activities shall be planned. Therefore, for the particular medical device being considered, the manufacturer shall establish and document a risk management plan in accordance with the risk management process. The risk management plan shall be part of the risk management file.		P
	This plan shall include at least the following:		--
	a) the scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases for which each element of the plan is applicable;		P
	b) assignment of responsibilities and authorities;		P
	c) requirements for review of risk management activities;		P
	d) criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated;		P
	e) verification activities;		P

EN ISO 14971			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	f) activities related to collection and review of relevant production and post-production information.		P
3.5	Risk management file		P
4	Risk analysis		P
4.1	Risk analysis process		P
	Risk analysis shall be performed for the particular medical device as described in 4.2 to 4.4. The implementation of the planned risk analysis activities and the results of the risk analysis shall be recorded in the risk management file.		P
4.2	Intended use and identification of characteristics related to the safety of the medical device		P
	For the particular medical device being considered, the manufacturer shall document the intended use and reasonably foreseeable misuse. The manufacturer shall identify and document those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. This documentation shall be maintained in the risk management file.		P
4.3	Identification of hazards		P
	The manufacturer shall compile documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions.		P
	This documentation shall be maintained in the risk management file.		P
4.4	Estimation of the risk(s) for each hazardous situation		P
	Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation shall be considered and the resulting hazardous situation(s) shall be recorded.		P
	Any system used for qualitative or quantitative categorization of probability of occurrence of harm or severity of harm shall be recorded in the risk management file.		P
5	Risk evaluation		P

EN ISO 14971			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	The manufacturer shall decide, using the criteria defined in the risk management plan, if risk reduction is required. If risk reduction is not required, the requirements given in 6.2 to 6.6 do not apply for this hazardous situation (i.e., proceed to 6.7). The results of this risk evaluation shall be recorded in the risk management file.		P
6	Risk control		P
6.1	Risk reduction		P
6.2	Risk control option analysis		P
	The manufacturer shall identify risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level.		P
	The manufacturer shall use one or more of the following risk control options in the priority order listed:		P
	during risk control option analysis, the manufacturer determines that required risk reduction is not practicable, the manufacturer shall conduct a risk/benefit analysis of the residual risk		P
6.3	Implementation of risk control measure(s)		P
	Implementation of each risk control measure shall be verified. This verification shall be recorded in the risk management file.		P
	The effectiveness of the risk control measure(s) shall be verified and the results shall be recorded in the risk management file.		P
	Compliance is checked by inspection of the risk management file.		P
6.4	Residual risk evaluation		P
	After the risk control measures are applied, any residual risk shall be evaluated using the criteria defined in the risk management plan. The results of this evaluation shall be recorded in the risk management file.		P
6.5	Risk/benefit analysis		P

EN ISO 14971			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to 6.6.		P
	For risks that are demonstrated to be outweighed by the benefits, the manufacturer shall decide which information for safety is necessary to disclose the residual risk.		P
6.6	Risks arising from risk control measures		N
	The effects of the risk control measures shall be reviewed with regard to:		N
	a) the introduction of new hazards or hazardous situations		N
	b) whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures		N
	The results of this review shall be recorded in the risk management file		N
6.7	Completeness of risk control		P
	The manufacturer shall ensure that the risk(s) from all identified hazardous situations have been considered. The results of this activity shall be recorded in the risk management file.		P
7	Evaluation of overall residual risk acceptability		P
	the manufacturer shall decide if the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan		P

EN ISO 14971			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk. If this evidence supports the conclusion that the medical benefits outweigh the overall residual risk, then the overall residual risk can be judged acceptable. Otherwise, the overall residual risk remains unacceptable.		P
	For an overall residual risk that is judged acceptable, the manufacturer shall decide which information is necessary to include in the accompanying documents in order to disclose the overall residual risk.		P
8	Risk management report		P
9	Production and post-production information		P
	The manufacturer shall establish, document and maintain a system to collect and review information about the medical device or similar devices in the production and the post-production phases.		P
	When establishing a system to collect and review information about the medical device, the manufacturer should consider among other things:		P
	a) the mechanisms by which information generated by the operator, the user, or those accountable for the installation, use and maintenance of the medical device is collected and processed; or		P
	b) new or revised standards.		N
	The system should also collect and review publicly available information about similar medical devices on the market.		P

EN 1041			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
4	Requirements		P
4.1	General		P
	Product information and labelling shall be part of risk management procedures		P
4.2	Units, symbols and colours		P
	Units used shall be SI units as specified in ISO 1000 or any other legal units.		P
	Symbols and safety-related identification colours shall be explained in the information supplied unless they are taken from harmonized standards, e.g. EN 980.		P
4.3	Language and country identifiers		P
	If the manufacturer decides to identify the language used in the information provided, for example to indicate to users the appropriate language in a multilingual document, this shall be done using the language codes given in ISO 639-1 and/or the plain text of the language (e.g. .English.).		P
4.4	Dates		P
4.5	Device nomenclature		P
4.5.1	Identifiers of nomenclature		P
4.5.2	Device common terms		P
	When it is appropriate to identify collective terms for medical devices in the information supplied, for example common technology or common materials of construction, this shall be done using the terms and codes set out in CEN/TR 15133		P
4.5.3	Batch code; lot number; batch number; lot code		P
	These shall consist of alphanumeric characters but may also be presented by other means, for example by using machine-readable codes.		P
5	Requirements for provision of information		P
5.1	General		P

EN 1041			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	Any means of provision of information with medical devices shall take into account the intended users, the conditions of use and any issues specific to individual device types that are necessary for the safe and effective use of the device. This shall apply regardless of whether the specific requirements listed below apply to the device.		P
5.2	Specific requirements		P
5.2.1	Applicability		P
	These specific requirements shall be applicable to all devices to the extent that they are applicable to the specific device type concerned and to the means of provision of the relevant information. For example, the requirement to allow for a .use by. date is not applicable to devices that do not bear a .use by. date.		P
5.2.2	Accessibility		P
	The information presented with a device shall be accessible to intended users taking into account their age, education, knowledge and training.		P
5.2.3	Legibility		P
	Information intended for visual recognition shall be easily legible when viewed using normal vision, corrected if necessary, taking into account the specific size and conditions of use of the particular device.		P
5.2.4	Availability		P
	Information shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.		P
5.2.5	Security		P
	As far as practicably possible, the medium of information provision shall be protected from corruption, degradation and deliberate change by those other than the manufacturer, whether malicious or not		P
5.2.6	Changes to information provided		P
	Any changes to information provided for existing users shall be clearly communicated if they are important for patient safety.		P

EN 1041			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
6	Documentation		P
	Documentation relating to information provided shall be maintained in the technical documentation(s) relating to the device(s) that are the subject of the information. This may take the form of a specific section holding all the documentation or, alternatively, references to parts of a larger document where the information may be found, such as a quality manual.		P

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
3	General principles applying to biological evaluation of medical devices		P
3.1	The selection and evaluation of any material or device intended for use in humans requires a structured programme of assessment.		P
3.2	In the selection of materials to be used in device manufacture, the first consideration should be fitness for purpose with regard to characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological and mechanical properties.		P
3.3	The following should be considered for their relevance to the overall biological evaluation of the device:		--
	a) the material(s) of manufacture;		P
	b) intended additives, process contaminants and residues;		N
	c) leachable substances;		N
	d) degradation products;		P
	e) other components and their interactions in the final product;		P
	f) the properties and characteristics of the final product.		P
3.4	Tests to be used in biological evaluation, and the interpretation of the results of such tests, should take into account the chemical composition of the materials, including the conditions of exposure and the nature, degree, frequency and duration of exposure of the device or its constituents to the body. By following these principles, devices can be categorized to facilitate the selection of appropriate tests (see Clause 4). This part of ISO 10993 is concerned with the tests to be carried out on materials and/or the final product.		P
3.5	All potential biological hazards should be considered for every material and final product, but this does not imply that testing for all potential hazards will be necessary or practical (see Clause 6).		P
3.6	Any in vitro or in vivo tests shall be based on end-use applications and appropriate good laboratory practice followed by evaluation by competent informed persons.		P

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
3.7	The materials or final product shall be considered for biological re-evaluation if change occurs:		P
3.8	The biological evaluation performed in accordance with this part of ISO 10993 should be considered in conjunction with the nature and mobility of the ingredients in the materials used to manufacture the device and other information, other non-clinical tests, clinical studies and post-market experience for an overall assessment.		P
4	Categorization of medical devices		P
4.1	General		P
4.2	Categorization by nature of body contact		P
4.2.1	Non-contact devices		P
	Medical devices that do not contact the patient's body directly or indirectly are not included in the scope of ISO 10993.		P
4.2.2	Surface-contacting devices		P
	These include medical devices in contact with the following surfaces:		--
	a) skin: devices that contact intact skin surfaces only; examples include electrodes, external prostheses, fixation tapes, compression bandages and monitors of various types;		P
	b) mucosal membranes: devices that contact intact mucosal membranes; examples include contact lenses, urinary catheters, intravaginal and intraintestinal devices (stomach tubes, sigmoidoscopes, colonoscopes, gastroscopes), endotracheal tubes, bronchoscopes, dental prostheses, orthodontic devices and intrauterine devices;		N
	c) breached or compromised surfaces: devices that contact breached or otherwise compromised body surfaces; examples include dressings, healing devices and occlusive patches for ulcers, burns and granulation tissue.		N
4.2.3	External communicating devices		N
	These include medical devices in contact with the following application sites:		N

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	a) blood path, indirect: devices that contact the blood path at one point and serve as a conduit for entry into the vascular system; examples include solution administration sets, extension sets, transfer sets and blood administration sets;		N
	b) tissue/bone/dentin: devices that contact tissue, bone or pulp/dentin systems; examples include laparoscopes, arthroscopes, draining systems, dental cements, dental filling materials and skin staples;		N
	c) circulating blood: devices that contact circulating blood; examples include intravascular catheters, temporary pacemaker electrodes, oxygenators, extracorporal oxygenator tubing and accessories, dialysers, dialysis tubing and accessories, haemoadsorbents and immunoadsorbents.		N
4.2.4	Implant devices		N
	These include medical devices in contact with the following application sites:		N
	a) tissue/bone: 1) devices principally contacting bone; examples include orthopaedic pins, plates, replacement joints, bone prostheses, bone cements and intraosseous devices; 2) devices principally contacting tissue and tissue fluid; examples include pacemakers, drug supply devices, neuromuscular sensors and stimulators, replacement tendons, breast implants, artificial larynxes, subperiostal implants and ligation clips;		N
	b) blood: devices principally contacting blood; examples include pacemaker electrodes, artificial arteriovenous fistulae, heart valves, vascular grafts, internal drug-delivery catheters and ventricular assist devices.		N
4.3	Categorization by duration of contact		N
	Medical devices shall be categorized according to the duration of contact as follows:		--
	a) Limited exposure (A): devices whose single or multiple use or contact is likely to be up to 24 h;		N
	b) Prolonged exposure (B): devices whose single, multiple or long-term use or contact is likely to exceed 24 h but not 30 days;		N

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	c) Permanent contact (C): devices whose single, multiple or long-term use or contact exceeds 30 days.		N
5	Testing		P
5.1	General		P
5.2	Initial evaluation tests		P
5.2.1	General		P
5.2.2	Cytotoxicity		P
	With the use of cell culture techniques, these tests determine the lysis of cells (cell death), the inhibition of cell growth, and other effects on cells caused by medical devices, materials and/or their extracts. Cytotoxicity tests are described in ISO 10993-5.		P
5.2.3	Sensitization		P
	These tests estimate, using an appropriate model, the potential of medical devices, materials and/or their extracts for contact sensitization. These tests are appropriate because exposure or contact to even minute amounts of potential leachables can result in allergic or sensitization reactions. Sensitization tests are described in ISO 10993-10.		P
5.2.4	Irritation		P
	These tests estimate the irritation potential of medical devices, materials and/or their extracts, using appropriate sites for implant tissue such as skin, eye and mucous membrane in a suitable model. The test(s) performed should be appropriate for the route (skin, eye, mucosa) and duration of exposure or contact to determine irritant effects of devices, materials and potential leachables. Irritation tests are described in ISO 10993-10.		P
5.2.5	Intracutaneous reactivity		N
	These tests assess the localized reaction of tissue to medical device extracts. These tests are applicable where determination of irritation by dermal or mucosal tests are inappropriate (e.g. medical devices having access to the blood path). These tests may also be useful where extractables are hydrophobic. Intracutaneous reactivity tests are described in ISO 10993-10.		N

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
5.2.6	Systemic toxicity (acute toxicity)		N
	These tests estimate the potential harmful effects of either single or multiple exposures, during a period of less than 24 h, to medical devices, materials and/or their extracts in an animal model. These tests are appropriate where contact allows potential absorption of toxic leachables and degradation products.		N
	Pyrogenicity tests are included to detect material-mediated pyrogenic reactions of extracts of medical devices or materials. No single test can differentiate pyrogenic reactions that are material-mediated from those due to endotoxin contamination. Systemic toxicity tests are described in ISO 10993-11.		N
	Immunotoxicity tests should be considered only for devices where data from other sources is suggestive of immunotoxicological effects.		N
	Systemic toxicity tests may be included in subacute and subchronic toxicity test protocols and implantation test protocols.		N
5.2.7	Subacute and subchronic toxicity		N
	These tests determine the effects of either single or multiple exposures or contact to medical devices, materials and/or their extracts for a period not less than 24 h but not greater than 10 % of the total life-span of the test animal (e.g. up to 90 days in rats). These tests may be waived for materials with chronic toxicity data. The reason for waiving of the tests should be included in the final report. These tests should be appropriate for the route and duration of contact. Subchronic toxicity tests are described in ISO 10993-11.		N
5.2.8	Genotoxicity		N
	These tests use mammalian or non-mammalian cell culture or other techniques to determine gene mutations, changes in chromosome structure and number, and other DNA or gene toxicities caused by medical devices, materials and/or their extracts. Genotoxicity tests are described in ISO 10993-3.		N
5.2.9	Implantation		N

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	These tests assess the local pathological effects on living tissue, at both the gross level and microscopic level, of a sample of a material or final product that is surgically implanted or placed in an implant site or in a tissue appropriate to the intended application (e.g. special dental usage tests). These tests should be appropriate for the route and duration of contact. For a material, these tests are equivalent to subchronic toxicity tests if systemic effects are also investigated. Implantation tests are described in ISO 10993-6.		N
	Implantation test protocols may be expanded to include systemic toxicity tests, subacute and subchronic toxicity tests, and chronic toxicity tests.		N
5.2.10	Haemocompatibility		N
	These tests evaluate, using an appropriate model or system, the effects of blood-contacting medical devices or materials on blood or blood components. Specific haemocompatibility tests may also be designed to simulate the geometry, contact conditions and flow dynamics of the device or material during clinical applications.		N
	Haemolysis tests determine the degree of red blood cell lysis and the release of haemoglobin caused by medical devices, materials and/or their extracts in vitro. Haemocompatibility tests are described in ISO 10993-4.		N
5.3	Supplementary evaluation tests		N
5.3.1	General		N
5.3.2	Chronic toxicity		N
	These tests determine the effects of either single or multiple exposures to medical devices, materials and/or their extracts during at least 10 % of the life-span of the test animal (e.g. more than 90 days in rats). These tests should be appropriate for the route and duration of exposure or contact. Chronic toxicity tests are described in ISO 10993-11.		N
	Chronic toxicity tests may be included in subacute and subchronic toxicity test protocols and implantation test protocols.		N
5.3.3	Carcinogenicity		N

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	These tests determine the tumorigenic potential of medical devices, materials and/or their extracts from either single or multiple exposures or contacts during the major portion of the life-span of the test animal. These tests may be designed in order to examine both chronic toxicity and tumorigenicity in a single experimental study. Carcinogenicity tests should be conducted only if there are suggestive data from other sources. These tests should be appropriate for the route and duration of exposure or contact. Carcinogenicity tests are described in ISO 10993-3.		N
5.3.4	Reproductive and developmental toxicity		N
	These tests evaluate the potential effects of medical devices, materials and/or their extracts on reproductive function, embryonic development (teratogenicity), and prenatal and early postnatal development. Reproductive/developmental toxicity tests or bioassays should only be conducted when the device has potential impact on the reproductive potential of the subject. The application site of the device should be considered. Reproductive and developmental toxicity tests are described in ISO 10993-3.		N
5.3.5	Biodegradation		N
	Where the potential for resorption and/or degradation exists, corresponding tests may determine the processes of absorption, distribution, biotransformation and elimination of leachables and degradation products of medical devices, materials and/or their extracts. Biodegradation tests are described in ISO 10993-9.		N
6	Selection of biological evaluation tests		P
	Selection of biological evaluation tests		P
	Evaluation may include both a study of relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design.		P
	Table 1 identifies the initial evaluation tests that shall be considered for each device and duration category. Table 2 identifies the supplementary evaluation tests that shall be considered for each device and duration category.		P

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	Due to the diversity of medical devices, it is recognized that not all tests identified in a category will be necessary or practical for any given device. It is indispensable for testing that each device be considered on its own merits: additional tests not indicated in the table may be necessary.		P
	The tests considered and the rationale for selection and/or waiving of tests shall be recorded.		P
7	Assurance of test methods		P
7.1	Test method assurance		P
	The test methods used in the biological evaluation shall be sensitive, precise and accurate. The test results should be reproducible (interlaboratory) as well as repeatable (intralaboratory).		P
7.2	Continued assurance		P
	The assurance that a material is initially acceptable for its intended use in a medical device, and its continued acceptability in the long term, is an aspect of a quality management system.		P

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**

Table 1 — Initial evaluation tests for consideration

Medical device categorization by			**Biological effect**							
Nature of body contact (see 4.2)		**Contact duration (see 4.3) A — Limited (< 24 h) B — prolonged (24 h to 30 days) C — permanent (> 30 days)**	**Cytotoxicity**	**Sensitization**	**Irritation or intracutaneous reactivity**	**Systemic toxicity (acute)**	**Subacute and subchronic toxicity**	**Genotoxicity**	**Implantation**	**Hæ mocompatibility**
Category	**Contact**									
Surface device	Skin	A	×	×	×					
		B	×	×	×					
		C	×	×	×					
	Mucosal membrane	A	×	×	×					
		B	×	×	×					
		C	×	×	×		×	×		
	Breached or Compromised surface	A	×	×	×					
		B	×	×	×					
		C	×	×	×		×	×		
External communicating device	Blood path, indirect	A	×	×	×	×				×
		B	×	×	×	×				×
		C	×	×		×	×	×		×

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**

	Tissue/bone/dentin	A	×	×	×					
		B	×	×	×	×	×	×	×	
		C	×	×	×	×	×	×	×	
	Circulating blood	A	×	×	×	×				×
		B	×	×	×	×	×	×	×	×
		C	×	×	×	×	×	×	×	×
Implant device	Tissue/bone	A	×	×	×					
		B	×	×	×	×	×	×	×	
		C	×	×	×	×	×	×	×	
	Blood	A	×	×	×	×	×		×	×
		B	×	×	×	×	×	×	×	×
		C	×	×	×	×	×	×	×	×

Table 2 — Supplementary evaluation tests for consideration

Medical device categorization by			**Biological effect**			
Nature of body contact (see 4.2)		**Contact duration (see 4.3) A — Limited (< 24 h) B — prolonged (24 h to 30 days) C — permanent (> 30 days)**	**Chronic toxicity**	**Carcinogenicity**	**Reproductive/developmentl**	**Biodegradation**
Category	**Contact**					
Surface device	Skin	A				
		B				
		C				
	Mucosal membrane	A				
		B				
		C				
	Breached or compromised surface	A				
		B				
		C				
External communicating device	Blood path, indirect	A				
		B				
		C	×	×		
	Tissue/bone/dentin	A				
		B				
		C	×	×		
	Circulating blood	A				
		B				
		C	×	×		
Implant device	Tissue/bone	A				
		B				

EN ISO 10993-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**

		C	×	×		
	Blood	A				
		B				
		C	×	×		

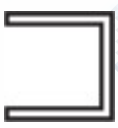
EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
4	General requirements		P
4.1	Proposal of symbols for adoption		P
	Symbols proposed for adoption in this document shall be validated in accordance with ISO 15223-2.		P
	Any symbol proposed for adoption in this document shall be applicable to a range of medical devices and have global or regional applicability.		P
4.2	Requirements for usage		P
	When risk management shows it to be appropriate for symbols to be used to convey information essential for proper use on the medical device, its packaging or in associated documentation, the symbols given in Table 1 may be used.		P
	Symbols that are registered in ISO 7000 shall comply with the graphical representation in ISO 7000, especially with respect to relative dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.		P
4.3	Other symbols		P
	Other standards specify additional symbols that are applicable to particular kinds or groups of medical devices or to particular situations. Examples of sources for such symbols are identified in the Bibliography. This listing is not exhaustive.		P
5	Symbols		P
	When appropriate, information essential for proper use shall be indicated on the medical device, its packaging, or in the associated documentation by using the corresponding symbols given in Table 1.		P
	A manufacturer may use any appropriate symbol regardless of category.		P
5.1	Manufacture		P

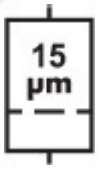
EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
5.1.1	Manufacturer 		P
5.1.2	Authorized representative in the European Community 		P
5.1.3	Date of Manufacture 		P
5.1.4	Use-by date 		P
5.1.5	Batch code 		P
5.1.6	Catalogue number 		P
5.1.7	Serial number 		P
5.2	Sterility		N
5.2.1	Sterile 		N

EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
5.2.2	Sterilized using aseptic processing techniques 		N
5.2.3	Sterilized using ethylene oxide 		N
5.2.4	Sterilized using Irradiation 		N
5.2.5	Sterilized using steam or dry heat 		N
5.2.6	Do not resterilize 		N
5.2.7	Non-sterile 		N
5.2.8	Do not use if package is damaged 		N
5.2.9	Sterile fluid path 		N
5.3	Storage		P

EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
5.3.1	Fragile, handle with Care 		P
5.3.2	Keep away from Sunlight 		N
5.3.3	Protect from heat and radioactive sources 		N
5.3.4	Keep dry 		P
5.3.5	Lower limit of temperature 		N
5.3.6	Upper limit of Temperature 		N
5.3.7	Temperature limit 		N

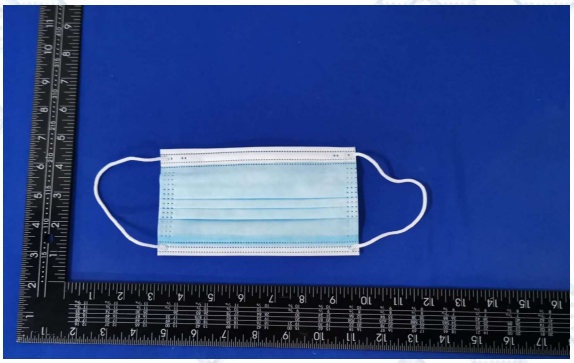
EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
5.3.8	Humidity Limitation 		N
5.3.9	Atmospheric pressure limitation 		N
5.4	Safe use		P
	Biological risks 		N
	Do not re-use 		N
	Consult instructions or use 		P
	Caution 		N
	Contains or presence of natural rubber latex 		N
5.5	IVD-specific		P

EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	In vitro diagnostic medical device 		P
	Control 		N
	Negative control 		N
	Positive control 		N
	Contains sufficient for <*n*> tests 		N
	For IVD performance evaluation only 		N
5.6	Transfusion/infusion		N
	Sampling site 		N
	Fluid path 		N

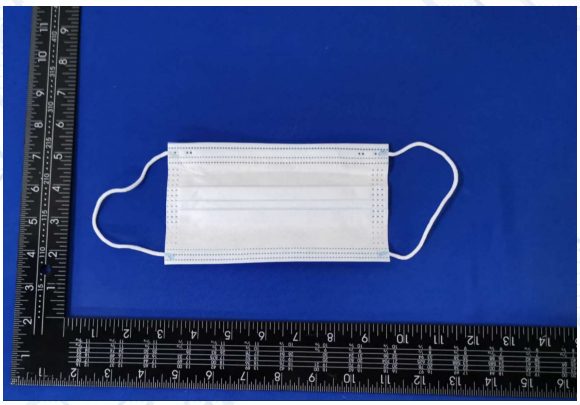
EN ISO 15223-1			
Clause	**Requirement – Test**	**Result - Remark**	**Verdict**
	Non-pyrogenic 		N
	Drops per milliliter 		N
	Liquid filter with pore Size 		N
	One-way valve 		N
5.7	Others		P
	Patient number 		P

Appendix 1

Photo of EUT



A.1



A.2