Review Report –审查报告–검토 보고서– Rapport d'Evaluation

CE Documentation Review

No. 0H200314.WPEUD07

Holder:

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Non-woven face mask **(no sterile)**

Model(s): M01, D02

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Test Report identified with the no. **XMT0201901540S/MDD**.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 14 March 2020

Expiry date: 13 March 2025

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Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0H200327M.WPE0382

Certificate's Holder:

Certification ECM Mark:

Type Approved

Product: Disposable FFP2 Face Mask

Model(s): F01, F02

Verification to: Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

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WUHAN PROTECT EQUIMENT CO.,LTD.

CE Technical Documents

Product name: Non-woven face mask (no sterile)

Applied Directive : Medical Device Directive (93/42/EEC+2007/47/EC)

Document No.: XMT0201901540S/MDD

Revision: V0

Compiled by: (Name/Title/Dept.)	Sadie	Date:	2020. 03. 12
Reviewed by (Name/Title/Dept.)	Lhm	Date:	2020. 03. 12
Approved by: (Name/Title/Dept.)	Jimmy	Date	2020. 03. 12

Contents

§1. Company and product introduction

§1.1 Overview our company

§1.2 Overview our product

Intended use:
Non-woven face mask (no sterile): Block the pollution of saliva, droplets and virus
Regarding the whole family of the series, they can be divided into various different groups.

§1.3 Classification of the product and application method

1) Classification of the product
Classification of the product According to the ANNEX IX of MDD 93/42/EEC rules Ⅰ, the product is subject to: Class Ⅰ
Product name: **Non-woven face mask (no sterile)**

2) Application method
The application channel for product certification is determined to be Annex VII (EC Declaration of Conformity)

§2. Checklist of Essential Requirement

Clause	Description	N/A	Standard/Sub-clause(s)	Report/Document
1	**General requirements**			
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will 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. This shall include: • reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and • consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)	A	EN ISO 14971：2012	Risk management report
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: – eliminate or reduce risks as far as possible (inherently safe design and construction), – where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, – inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	EN ISO 14971：2012	Risk management report
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	A	EN 14683:2019	Test report
4.	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients 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.	A	EN ISO 14971：2012	Risk management report
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	A	EN ISO 14971：2012 EN 1041：2008 EN 15223-1:0216 EN 14683:2019	

6.	Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.	N		
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	N	--	--
II	**Requirements regarding design and construction**			
7. 7.1.	**Chemical, physical and biological properties** The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to: – the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, – the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. – Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	N	--	--
7.2.	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	N	--	--
7.3.	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	N	--	--
7.4.	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004[1] on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as	N	--	--

	determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing this opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.			
7.5.	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC[2] of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[3] If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC[2], these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	N	--	--
7.6.	Devices must be designed and manufactured in such a way as to reduce, as much as possible, 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.	N	--	--
8. 8.1.	**Infection and microbial contamination** The devices and manufacturing processes must be designed in such as way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy	N	--	--

[2] Internal note: replaced by (EC) 1272/2008

[3] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

	handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.			
8.2.	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	N	--	--
8.3.	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	N	--	--
8.4.	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	N	--	--
8.5.	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	N	--	--
8.6.	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	N	--	--
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	N	--	--
9. 9.1.	**Construction and environmental properties** If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	N	--	--
9.2.	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: – the risk of injury, in connection with their physical features, including the volume/pressure ration, dimensional and where appropriate ergonomic features, – risks connected with reasonably foreseeable environmental conditions, such as magnetic fields,	A	EN ISO 14971：2012	Risk management report

	external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, – the risks of reciprocal interference with other devices normally used in the investigations of for the treatment given, – risks arising when maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
9.3.	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion	N	--	--
10. 10.1.	**Devices with a measuring function** Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	N	--	--
10.2.	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	N	--	--
10.3.	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	N	--	--
11. 11.1. 11.1.1	**Protection against radiation** *General* Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	N		
11.2. 11.2.1	*Intended radiation* Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	N	--	--
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	N	--	--
11.3.	*Unintended radiation*	N		

11.3.1	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.			
11.4. 11.4.1	*Instructions* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse of eliminating the risks inherent in installation.	N	--	--
11.5. 11.5.1	*Ionizing radiation* Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	N	--	--
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	N	--	--
11.5.3	Devices emitting ionizing radiation, 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 and energy and where appropriate the quality of radiation.	N	--	--
12. 12.1.	**Requirements for medical devices connected to or equipped with an energy source** Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	N	--	--
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.			
12.2.	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	N	--	--
12.3.	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	N	--	--
12.4.	Devices intended to monitor one or more clinical parameters of a patient must 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.	N	--	--
12.5.	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields, which could impair the operation of other devices or equipment in the usual environment.	N	--	--

12.6.	*Protection against electrical risks* Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	N	--	--
12.7. 12.7.1	*Protection against mechanical and thermal risks* Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risk connected with, for example, resistance, stability and moving parts.	A	EN 14683:2019 EN ISO 14971：2012	Test report Risk management report
12.7.2	Devices must 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.	N	--	--
12.7.3	Devices must 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.	N	--	--
12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	N	--	--
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	N	--	--
12.8. 12.8.1	*Protection against the risks posed to the patient by energy supplies or substances* Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	N	--	--
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate, which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	N	--	--
12.9.	The function of the controls and indicators must 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 must be understandable to the user and, as appropriate, the patient.	N	--	--
13.	**Information supplied by the manufacturer** Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	A	EN 1041：2008 EN 15223-1:0216	Instruction for use Labeling

13.1.	This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.			
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	EN 15223-1:0216	Labeling
13.3.	(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community; (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the work 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and the month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization. (n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	A	EN 15223-1:0216	Labeling
13.4.	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	A	EN 1041: 2008 EN 15223-1:0216	Instruction for use Labeling

13.5.	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	N	---	---
13.6.	Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for it intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e)where appropriate, information to avoid certain risks in connection with implantation of the device; (f)information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of he device to be resterilized, and any restriction on the number if reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I). If the device bears an indication that the device 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 If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in	A	EN 1041: 2008	Instruction for use

	pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; (n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function. (q) date of issue or the latest revision of the instructions for use.			

§3. Risk management report

Risk Analysis

COMPANY NAME:	
COMPANY ADDRESS:	[illegible]
PRODUCT:	Non-woven face mask (no sterile)
MODEL:	M01, D02
Accessories:	/
PROCEDURE:	EN ISO 14971:2012
RESULT:	All risks associated with the identified hazards have been evaluated. After appropriate measures to reduce these risks have been taken, the overall level of risk of the product is acceptable with regard to the intended application and use of the application.

Compiled by: (Name/Title/Dept.) Sadie Date: Mar.12, 2020

Reviewed by (Name/Title/Dept.) [signature] Date: Mar.12, 2020

Approved by: (Name/Title/Dept.) [signature] Date: Mar.12, 2020

Identification of qualitative and quantitative characteristics (acc. To EN ISO 14971:2012, cl. 4.2)

1	Intended use and how to use	Block the pollution of saliva, droplets and virus
2	Intended to contact patient or other person	Surface contact
3	Intended to be implanted ?	No
4	Materials/components used	Silicon rubber
5	Energy to/from patient	No
6	Substances to /from patient	No
7	Biological materials processed	No
8	terile/Intended to be sterilized	No
9	routinely cleaned and disinfected by the user	Routine cleaning，use clean water to clean
10	Modify patient environment	No
11	Measurements	No
12	Interpretative	
13	use in conjunction with medicines or other medical technologies	use in conjunction with medicines，temporary containment all kinds of medicines.
14	Unwanted outputs of energy or substances	No
15	Susceptible to environmental influences	No
16	influence the environment	No
17	Consumables/accessories associated	Consumables
18	Routine maintenance/calibration	No
19	Software	No
20	Restricted "shelf-life":	Yes，1 years
21	Delayed and/or long-term use effect	No，only a little aging to the materials
22	Mechanical forces	Yes
23	Lifetime of the device determined	Material life time
24	Single use/re-use	Re-use
25	safe decommissioning or disposal	No
26	Special training required to install or use	Yes
27	How to provide safe use information?	Yes，Product manual provides safety information
28	new manufacturing	No

	processes need to be established or introduced	
29	successful application of the medical device critically dependent on human factors, such as user interface	Yes
29.1	Might the user interface design feature force using mistake?	No
29.2	Could the medical device be used in the use error environment, that caused by distraction?	No
29.3	Are there ponteses or accessories in the medical device.	No
29.4	Is there a control interface in the medical device?	No
29.5	Displays the medical device information?	No
29.6	Is the medical device controlled by menu?	No
29.7	Is the medical device used by the person, who has special needs?	No
29.8	Could the UI controlled by launching user?	No
30	Is there warming system in the medical device?	No
31	In which way could the medical device be used Intentionally?	No
32	Is there patients' key data in medical device?	Yes
33	Is the medical device intended to be moveable or portable type?	Portable type
34	Depends the use of medical device on basic performance?	No

No.	Hard		Risk Evaluation		Risk Reduction Measure		Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL			

D3. Biological hazards									
1	Bio-contamination	No	1	1	1	1			Yes
2	Bio-incompatibility	No	1	1	1	1			Yes
3	Incorrect formulation(chemical composition)	No	1	1	1	1			Yes
4	Toxicity	No cleaning	2	1	1	1	Routine cleaning	Biological Test report	Yes
5	allergenicity	No	1	1	1	1			Yes
6	mutagenicity	No	1	1	1	1			Yes
7	oncogenicity	No	1	1	1	1			Yes
8	teratogenicity	No	1	1	1	1			Yes
9	Carcinogenicity	No	1	1	1	1			Yes
10	Re-and/or cross-infection	No (single patient use only)	1	1	1	1	Only can be used by one patient		Yes
11	pyrogenicity	No	1	1	1	1			Yes
12	Inability to maintain hygienic safety	It can be maintained by cleaning	1	1	1	1	Clean the product according to the cleaning method in user manual		Yes
13	Degradation	Use for a long time may oxidation	1	1	1	1	Make shelf life time for this product		Yes
D6. Hazards related to the use of the device and contributory factors									
1	Inadequate labeling	The exact product item can not fit the item number labeling	2	1	1	1	Product pictures shown on the package	If the user doesn't use the right item, it may reduce the effectiveness of inhalation of medicine	Yes
2	▪ Inadequate operating instructions inadequate specification of accessories ▪ inadequate specification of pre-use checks ▪ over-complicated operating instructions ▪ inadequate specification of service and maintenance	Patients can not use this product properly	2	1	1	9	Make easy understanding user manual with operating pictures	If the patients can not use this product properly, it may reduce the effectiveness of medicine inhalation	Yes
3	Use by unskilled/untrained personnel	Child or infant use it by themselves	1	2	1	1	Notes should be shown on the user manual as follows: "child or infant which can not use this product by themselves should complete the inhalation under the help of adults or doctors"	User's manual	Yes
4	Reasonably foreseeable misuse	Some patients may press the MDI before they put the mask over their mouth and nose very	2	1	1	3	Patients should use this product according the use manual step by step	User's manual	Yes

		tight								
5	Insufficient warning of side effects	No side effect	1	1	1	1				Yes
6	Inadequate warning of hazards likely with re-use of single use devices	This product is reusable	1	1	1	1				Yes
7	Incorrect measurement and other metrological aspects	No measurement function	1	1	1	1				Yes
8	Incompatibility with consumables/accessories/other devices	This product may not fit the mask or back piece made by other companies	1	1	1	1	All the accessories are made by our company			Yes
9	sharp edges or points	It may have a little sharp edges during the process of manufacturing	1	1	1	1	Control every manufacturing process, the parts with sharp edges can not be used for this product			Yes
B2. Additional hazards to in vitro diagnostic medical devices										
1	Batch inhomogeneity, batch-to-batch inconsistency	It may have a little color differences of back piece	1	1	1	1	Control material weight while burdening			Yes
2	Common interfering factors	No	1	1	1	1				Yes
3	Carry-over effects	No	1	1	1	1				Yes
4	Specimen identification errors	It may affect confusion	1	1	1	1	Identify by different people for at least 3 times			Yes
5	Stability problems (in storage, in shipping, in use, after first opening of the container)	This product has very good stability in storage, in shipping, in use, after first opening of the container	1	1	1	1				Yes
6	Problems related to taking, preparation and stability of speciments	No	1	1	1	1				Yes
7	Inadequate specification of prerequisites	No	1	1	1	1				Yes
8	Inadequate test characteristics	It may make wrong result	1	1	1	1	Control testing SOP			Yes
Post-production information										
	Post-production experience: This product components are very simple, so does the operation principle, less risk factors, risk has fallen into routine acceptable level by adopting the above risk lowering measures.									
	Review of risk management experience: All the risks involved in this report were already evaluated, after taking lower the risk of corresponding measures (control engineering in size and product manual detail), for the products intended application and intended use, the overall level of risk has been reduced to acceptable levels, so the products are safe.									

Abbreviations used

RE	Risk Evaluation
S	Severity (10 –very severe, 1 –not severe)
O	Occurrence (10 –often, 1 –never)
D	Detection (10 –impossible to detect before risk occurs, 1 –will be certainly detected before risk occurs)
RL	Risk Level = Severity ×Occurrence × Detection 1-9: neglectable risk, no further actions; 9-24: moderate: minimal risk, preventive action recommended; 25-48: moderate risk, preventive action required; >48: risk is usually not acceptable
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes - if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

SEVERITY of Effect	Ranking
Injure a customer or employee	10
Be illegal	9
Render product or service unfit for use	8
Cause extreme customer dissatisfaction	7
Result in partial malfunction	6
Cause a loss of performance which is likely to result in a complaint	5
Cause minor performance loss	4
Cause a minor nuisance but can be overcome with no performance loss	3
Be unnoticed and have only minor effect on performance	2
Be unnoticed and not affect the performance	1

PROBABILITY of Failure	Failure Prob	Ranking
Very High: Failure is almost inevitable	>1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is unlikely	<1 in 1,500,000	1

Detection	Likelihood of DETECTION by Design Control	Ranking
Absolute Uncertainty	Defect caused by failure is not cetectable	10
Very Remote	Occasional units are checked for defect	9
Remote	Units are systematically sampled and inspected	8
Very Low	All units are manually inspected	7
Low	Manual inspection with mistake-proofing modifications	6
Moderate	Process is monitored(SPC) and manually inspected	5
Moderately High	SPC is used with an immediate reaction to out of control conditions	4
High	SPC as above with 100% inspection sourrounding out of control conditions	3
Very High	All units are automatically inspected	2
Almost Certain	Defect is obvious and can be kept from affecting the customer	1

Clause	Requirement-Test	Result-Remark	Verdict
	EN 14683:2019 Medical face masks —Requirements and test methods		
1	**Scope**		-
	This European Standard specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.		P
2	**Normative references**		-
	The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.		P
3	**Terms and definitions**		-
	For the purposes of this document, the following terms and definitions apply.		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		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	<29.4	P
3.4	colony forming unit (cfu)		-
	unit by which the culturable number of micro-organisms is expressed		P
3.5	cleanliness		-
	freedom from unwanted foreign matter	Clean	P
3.5.1	cleanliness — microbial		-

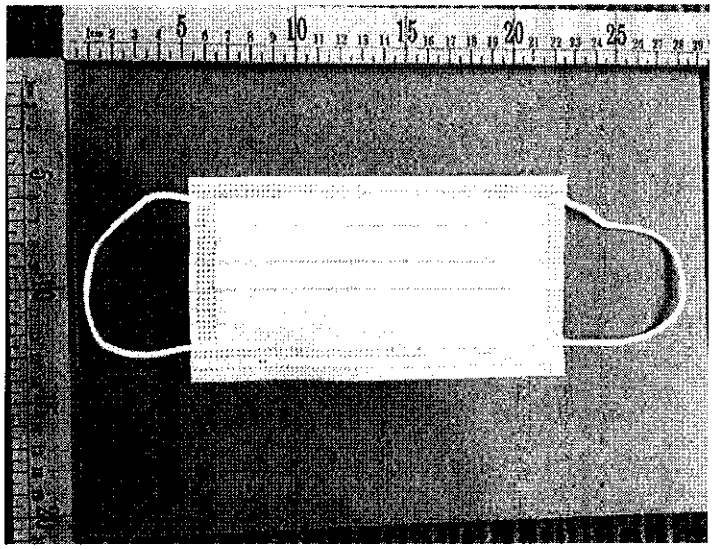
	freedom from population of viable micro-organisms on a product and/or a package		P
3.5.2	cleanliness — particulate matter		-
	freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact	Comply with the requirements	P
3.6	infective agent		-
	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		P
3.8	aerosol		-
	gaseous suspension of solid and/or liquid particles, the particles having a negligible falling velocity		P
3.9	filter		-
	material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air	Meet the requirements	P
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 II	P
5	**Requirements**		-
5.1	General		-
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		-

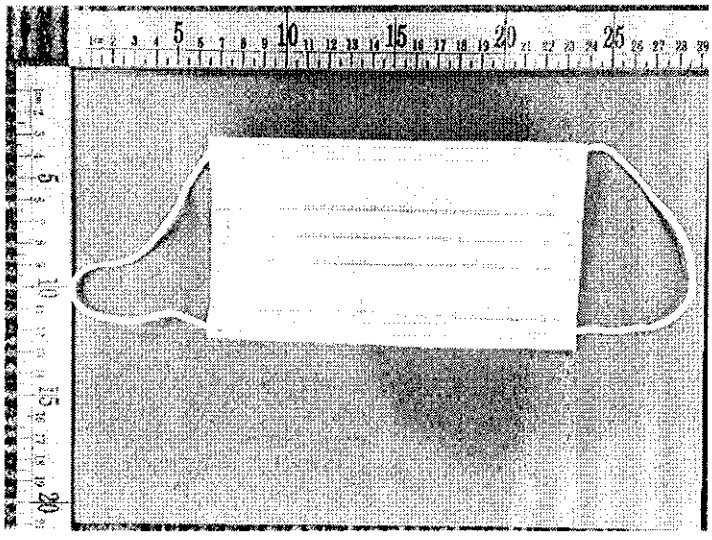
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
5.2	Performance requirements		-
5.2.1	General		-
	All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.	Meet the requirements	P
5.2.2	Bacterial filtration efficiency (BFE)		-
	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.	98.9%	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.	Easy to breathe through	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 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.	26cfu/g	P
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.	Meet the request ofBiocompatibility	P

5.2.7	Summary of performance requirements		-
	Table 1 — Performance requirements for medical face masks Test / Type I[a] / Type II / Type IIR Bacterial filtration efficiency (BFE), (%) / ≥ 95 / ≥ 98 / ≥ 98 Differential pressure (Pa/cm²) / < 29.4 / < 29.4 / < 49.0 Splash resistance pressure (kPa) / Not required / Not required / ≥ 16.0 Microbial cleanliness (cfu/g) / ≤ 30 / ≤ 30 / ≤ 30 [a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.		P
6	**Labelling and information to be supplied**		-
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied in addition: a) number of this European Standard; b) type of mask (as indicated in Table 1). EN ISO 15223-1 and EN 1041 should be considered.		P

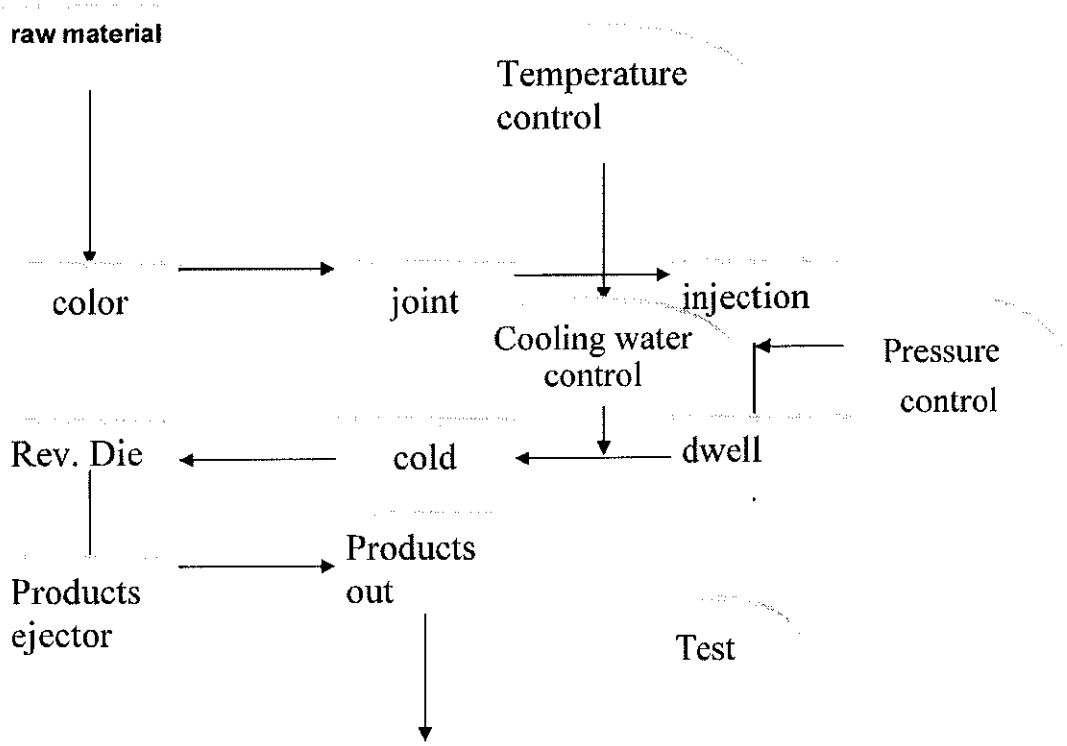
§5. Comprehensive description

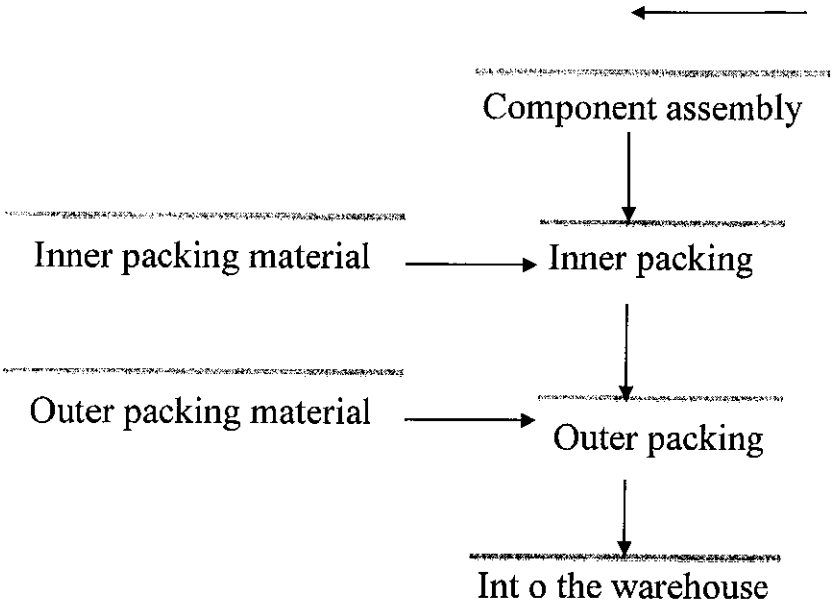
Name: Non-woven face mask (no sterile)





(2) Production process and quality control point





（3） Description of packaging

The outer packaging of the products is carton; the pollution of the carton is very little to the environment. And the material of the carton can be re-used.
The inner packaging of the products is the plastic bag. The bag can keep the products clean during the transport and can avoid the products polluted.
The plastic bag can be re-used to reduce the pollution of the environment.

§6. Clinical investigation

6.1 Summary of product
Product name: N
Manufacturer:

6.2. The description of the machine and intended use
Non-woven face mask (no sterile): Block the pollution of saliva, droplets and virus.

6.3 Document retrieval should be proceed according to the below protocols.
a) The scope of document retrieval: the relevant documents covering the security, performance of Mask and adverse events.
b) Methods
(i) The date of document retrieval: 11th Mar 2020
(ii) Document retrieved by Jason Xing
(iii) The scope of retrieving time: The information about the security and performance of digital electronic sphygmomanometer and adverse events in recent 20 years.
(iv) The resource of the documents"
- The website of America's FDA
- The website of state' s SFDA
- Wanfang datebase
- Database of adverse events reports
(v) The details of database retrieval:
- Retrieving the key words: Mask, performance; inhalers, adverse events.

Note: If the above effect of key words retrieval is not good, the word "inhalers" should be the keywords. Then we should have initial selection to the retrieved documents in accordance with the scope of clinic evaluation.
- The media used: computer networks
(vi) Selection criteria of the document: Have initial selection on the basis of the correlation of the document's content and scope of clinic evaluation.
c) Output
(i) Attach the copes of the retrieved document
(ii) The process of choosing the documents
6.4 Conclusion
The production technique, process of Mask are mature and reliable , the products are widely used in hospitals and clinical fields, no complaint on performance or other nonconformity received, no one case of user or patient death or depravation of health.

So the product sales history achievement and certification by 3rd party on production competence, environment and quality system showed that: the production technique environment of this product can ensure the safety and intended use of product.

In the 《 risk report 》 compiled by our company, the potential risk existing in raw material, production process were analyzed, and listed the potential risk and effective control measures, the report showed that the product risks were reduced to acceptable level, the use value is far more than risk. Every year we will make a regular analysis according to post-market surveillance.

Summarily, the use value of Stretchers manufactured in our company is far more than risk, can be used as medical device.

§7. Labeling

According to MDD93/42/ECC, symbols, terminologies and information that are included in label of filter for single use with CE mark are accordance with EN 15223-1:0216 and EN1041:2008.

Devices sold in domestic market, the master document's language should be Chinese (excluding labels, the instruction for use).

Devices sold in the EC market, the master document's language should be English and other languages used by EC(excluding labels, the instruction for use).

6.1 design of the label:

The product produced by our company labeled with the following information:

a. Product name, type and quantity
b. CE mark
c. Batch number, production date
d. Manufacturer name
e. Manufacturer address
f. Name and address of the EC representative

6.2 conformity and accuracy of the label:

According to the requirements of MDD93/42 EEC, the medical products supplied to European market should be labeled in line with the specification.

Label content:

Product name, Type;

Symbol 

for"BATCH CODE" (the symbol should be attached with batch code and be close to the graph, batch code, lot number and batch number).

Examples: LOT YYYY-MM

Symbol  for "DATE OF MANUFACTURE" (the symbol should be close to the number)

Examples:  YYYY-MM

Symbol  for "MANUFACTURE"

Symbol 

for "EC REPRESENTATIVE"

Symbol  for "ATTENTION, SEE INSTRUCTIONS FOR USE"

Attaching CE marking indicates that:

This device meets the basic requirements of MDD.

This device can be legally put on the market of Europe.

This device has passed a relevant conformity estimation program.

There are two types of CE Marking attached on the medical devices: CE marking without identified number of Notified Body and CE marking with identified number of Notified Body. CE marking without identified number only apply to the Class I medical devices, which needn't to be sterilized and have no measure function.

§8. Use Manual

Product performance structure and composition: This product is made of non-woven fabric, BFE99, melt blown cloth and other hot pressing

§9. List of applied standards

No.	File No.	Version	File Title
1	EN ISO 9001	2015	Quality Management System -Requirements
2	EN ISO 13485	2016	Medical Device - Quality Management System - Requirements for Regulatory Purposes
3	MDD 93/42/EEC	1993	Medical Device Product Safety Directive
4	EN ISO 14971	2012	Medical Device - Application of Risk Management in Medical Device
5	EN 15223-1	2016	Symbols Used on Labels of Medical Devices
6	EN 1041	2008	Terminology, Symbols and Information Related to Medical Devices – Information Provided by Manufacturers of Medical Devices
7	EN 62366	2008	Medical devices —Application of usability engineering to medical devices
8	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
9	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10	EN ISO 10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
11	EN 14683	2019	Surgical masks - Requirements and test methods

§10. Technical File Control

TCF is prepared by Quality department, reviewed by manager of quality department, and approved by general manager. Quality department shall review essential requirements every year to make sure that device with CE mark is safe and effective, and revise when necessary. Every changes of TCF should be reviewed and approved.

Quality department manages the process of TCF control, issuance, and change. The deportment is responsible for informing the notified body as well as European representative of the changes.

§11. Quality system control

In order to ensure the conformity of the series production, we have taken the related procedures mentioned below:

（1） Carry out the inspection for parts and components according to the TCF

Before the assemblies of the series production, the QC engineers of manufacturer has to check and inspect the technical specifications and intended functions of parts and components to ensure the correct use of them according to the contents of TCF and principle described in the related technical information.

(2) Carry out the inspection & testing for the products before packing

Before packing the products, the QC engineers of manufacturer have to do the necessary inspection and testing to ensure the conformity of related requirements.

(3) Carry out the inspection for the package.

After finishing the necessary inspection and testing for the products, an inspection for the packing has to be done to ensure the necessary elements being included in this packing before shipment.

(4) Provision for the change of design

Any change of the products described in this TCF must be checked in detail and written down again in the TCF by the designer of manufacturer if the change may effects the following:

a) Products' intended use is changed
b) A change in product performance
c) A change in product security features;
d) A change in product identification;
e) Products, a change in important and critical components
f) Products changed with the technology
g) Product features (including user action) or performance-related medical reasons, resulting in product recovery company system;
h) When the EU classification of the product when the rules changed;
i) Other (Notice agencies suggestions).

(5) Provision for the Quality Assurance

For the provisions of internal control measures to ensure the conformity of series production of the machines, manufacturer has built an internal quality control system in accordance with the international standard of ISO 13485.

EC Declaration of conformity

Council Directive 93/42/EEC &2007/47/EC on Medical Devices Directive

China

Certify that the product described is in conformity with the Medical Devices Directive 93/42/EEC&2007/47/EC as amended

Product Name:

Non-woven face mask (no sterile)

Item No:

M01, D02

The product has been assessed by the application of the following standards:

EN 14683:2019

2020.3.15

Issue place and date

Company stamp and Signature of authorized personnel