CE Technical File

Disposable Face Mask

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CE Technical File Contents

HC-CE-KZ1-1 Declaration of conformity

Manufacturer:	Name: Changzhou Huichun Medical Equipment Co., Ltd. Add: Sanhekou, Zhenglu Town, 213115 Changzhou, Jiangsu, People's Republic of China
European Representative:	Name: Shanghai International Holding Corp. GmbH (Europe) Add : Eiffestrasse 80, 20537 Hamburg Germany Tel: +49-40-2513175 Fax: +49-40-255726 E-mail: shholding@hotmail.com
Product Name	Disposable Face Mask
Model Number:	G type and X type
UMDNS-Code:	12447

Classification (MDD, Annex IX): Class I Rule 1

Conformity Assessment Route: **Annex VII**

We herewith declare that we follow the applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC, according to Rule 1 of Annex IX in MDD93/42/EEC, the face mask is Class I device, it can "CE" marked.

The product concerned has been designed and manufactured under a quality management system according to MDD93/42/EEC Annex VII.Following the procedure relating to the EC Declaration of Conformity set out in MDD93/42/EEC Annex VII This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices. Changzhou Huichun Medical Equipment Co., Ltd. takes full responsibility of the content of Declaration of Conformity.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Signature: _____
Name: Mr. Xiaobo Zheng
Place& Date: Changzhou, Jiangsu, China 2020-03-26
Position: General Manager

HC-CE-KZ1-2 Product introductions

1. Overview of product

The Disposable Face Mask is composed of face mask body, nasal clamp and mask belt. The inner layer is made of non-woven cloth with Waterproof function, the out layer of face mask body is made of normal non-woven cloth, the middle layer is made of melt spray material, the mask belt is made of elastic material or spandex, the nasal clamp is made of plastically bendable material. The product is non-sterile.

2. Intended use of product

Disposable Face Mask is intended for cover the user's mouse, nose and underjaw to prevent pollutants exhaled or ejected from oral and nasal cavity under normal medical environment without the risk of body fluid and spray.

3. Performances

The product is complying with requirements of YY/T 0969-2013 <Disposable Face Mask>. Main performance:

(1) Appearance smooth and clean, figure is fit, surface has no damage or dirty.

(2) The face mask covered on face can cover the nose, mouse and underjaw well.

(3) There is nasal clamp on face mask, it has plasticity, the nasal clamp length does not less than 8.0cm.

(4) The face mask is convenient to use, the minimum breaking load of mask body and mask belt is not less than 10N.

(5) The bacteria filtration rate is not less than 95%.

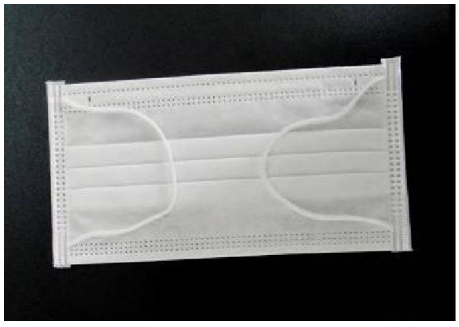
(6) The air exchange pressure difference of two sides of face mask △p is not more than 49Pa.

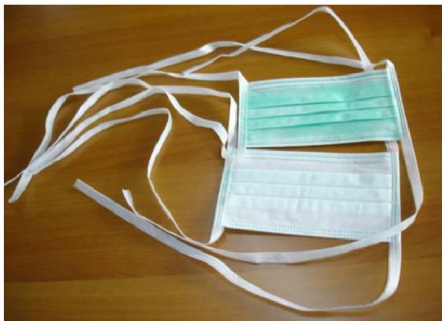
(7) The non-sterile type face mask bioburden is ≤100CFU/g.

4. Type of Product:

Type	Dimension (cm)	color	nasal clamp length (cm)	Ear tie length (cm)
G	17.5±0.3×9.5 ±0.3	white (W) /blue (B)	≥8.0	16.0±0.5
X				35.0±0.5

5. Product picture (for example)





6. Contraindications
Persons who sensitive to related materials shall be carefully to use this product.
Not use for wound treatment environment

7. Usage
(1) Peel the seal of package, take out the face mask, identify the inner side and outer side, pay attention do not contact the white side by hand.
(2) Close to face, hang the belt to two ears, place the mask clamp upon nose, pull the face mask crepe by two hands, press the clamp on nose by middle fingers of two hands, ensure the face mask cover the nose, mouse and underjaw.

8. Precautions
(1) This product is for single use, once open the primary package, use as soon as possible.
(2) The used product shall be treated according to medical waste requirement. Do not use if the package is damaged or expired.
(3) The used product shall be scrapped and destroyed.
(4) Pay attention to the information such as “Pay attention to check the expiry date”, “Do not use if the package is damaged or expired”.
(5)Read the instructions for use before use.

9. Storage conditions:
Indoor with related humidity not higher than 80%, without erosive gas, with good ventilation.

10. Life time of the product:
2 years.

11. Classification of product
According to Rule 1 of Annex IX in MDD93/42/EEC, the face mask is non-active device contact with human body surface, not sterile, is Class I device.

12. Conformity Assessment Route: MDD93/42/EEC Annex VII (Self-declaration)

HC-CE-KZ1-3Essential requirements checklist

1. List of applicable EN ISO, EN and ISO standards

S/N	Standard No.	Issue year	Title
1	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	93/42/EEC	2007	Medical Device Directives
3	ENISO10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4	ENISO10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
5	ENISO10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
6	EN ISO 14971	2012	Medical devices - Application of risk management to medical device
7	EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
8	EN 1041	2008	Information supplied by the manufacturer of medical devices
9	YY/T 0969	2013	Disposable Face Mask

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2. Essential requirements checklist

Essential requirements	A/N A	Standard	Manufacturers Compliance	Reasons if not applicable
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, 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 intended 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	HC-CE-KZ1-4 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:	A	EN ISO 14971:2012	HC-CE-KZ1-4 Risk management report	

– 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.				
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	YY/T 0969:2013	Total performance 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	HC-CE-KZ1-4 Risk management report HC-CE-KZ1-7 Clinical evaluation reports	
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	YY/T 0969:2013	Total performance test report	
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. 6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A	EN ISO 14971:2012	HC-CE-KZ1-4 Risk management report HC-CE-KZ1-7 Clinical evaluation reports	
7. Chemical, physical and biological properties 7.1. 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 modeling research whose validity has been demonstrated beforehand.'	A	YY/T 0969:2013 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010	Total performance test report Refer to Biocompatibility test report	
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.	NA			No residual requirement
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	A	EN ISO 14971:2012	HC-CE-KZ1-4 Risk management report	

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.				
'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 (*) 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 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 its 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. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into 21.9.2007 EN Official Journal of the European Union L 247/43 account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. 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	NA			The device is not to be a medicinal product

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 of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (*). 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, 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.	NA			No such substance
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.	A	EN ISO 14971:2012	HC-CE-KZ1-4 Risk management report	
8. Infection and microbial contamination 8.1. The devices and manufacturing processes must be designed in such a 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 handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	A	EN ISO 14971:2012 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010	HC-CE-KZ1-4 Risk management report Refer to Biocompatibility test report	
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 transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the	NA			No tissues of animal origin

manufacturing process. (2007/47/EC: the word 'transferable' shall be replaced by the word 'transmissible)				
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.	NA			The product is non-sterile
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	NA			The product is non-sterile
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	NA			The product is non-sterile
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.	NA			The product is non-sterile
9. Construction and environmental properties 9.1. 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.	NA			No combination
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 ratio, dimensional and where appropriate ergonomic features, — risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, 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 or for the treatment given, — risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	NA			No these cases
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 in 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.	NA			No these cases
10. Devices with a measuring function 10.1. 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.	NA			No measuring function

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.	NA			No measuring function
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 (1).	NA			No measuring function
11. Protection against radiation 11.1. General 11.1.1. 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.	NA			No radiation characteristics
11.2. Intended radiation 11.2.1. 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. 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.	NA			No radiation characteristics
11.3. Unintended radiation 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.	NA			No radiation characteristics
11.4. Instructions 11.4.1. 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 and of eliminating the risks inherent in installation.	NA			No radiation characteristics
12. Requirements for medical devices connected to or equipped with an energy source 12.1. 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. 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. 12.1b 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 principals of development lifecycle, risk management, validation and verification.	NA			Not connect to or equipped with an energy source
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.	NA			Not connect to or equipped with an energy source

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.	NA			Not connect to or equipped with an energy source
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.	NA			Not connect to or equipped with an energy source
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.	NA			Not connect to or equipped with an energy source
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.	NA			Not connect to or equipped with an energy source
12.7. Protection against mechanical and thermal risks 12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. Page 11 sur 33 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. 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. 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. 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.	NA			Not connect to or equipped with an energy source
12.8. Protection against the risks posed to the patient by energy supplies or substances. 12.8.1. 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. 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.	NA			Not connect to or equipped with an energy source
12.9. The function of the controls and indicators must be clearly specified on the devices. Where a device bears instruction required for its operation or indicates	NA			Not connect to or equipped with an energy

operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.				source
13. Information supplied by the manufacturer 13.1. 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. 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 and 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.	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
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 ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
13.3. The label must bear the following particulars: ‘(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;’	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(c) where appropriate, the word ‘STERILE’;	NA			The product is non-sterile
(d) where appropriate, the batch code, preceded by the word ‘LOT’, or the serial number;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
‘(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;’	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(g) if the device is custom-made, the words ‘custom-made device’;	NA			It is not ”custom-made device”
(h) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;	NA			Not for clinical investigations
(i) any special storage and/or handling conditions;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(j) any special operating instructions;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	

(k) any warnings and/or precautions to take;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(l) year of manufacture for active devices other than those covered by	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(e). This indication may be included in the batch or serial number;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
(m) where applicable, method of sterilization;	NA			The product is non-sterile
(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	NA			Not contain a human blood derivative
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 ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples	
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.	NA			The device is for single use, need not to detach
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);	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
(b) the performances referred to in Section 3 and any undesirable side-effects;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
(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;	NA			The device need not to maintenance and calibration
(e) where appropriate, information to avoid certain risks in connection with implantation of the device;	NA			It is not an implanted device
(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	NA			The product is non-sterile
(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 the device to be resterilized, and any restriction on the number of 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	NA			The device is for single use

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.);	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
(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:	NA			Not emitting radiation
(k) precautions to be taken in the event of changes in the performance of the device;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
(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 pressure, acceleration, thermal ignition sources, etc.;	NA			No effect of magnetic fields, external electrical influence, electrostatic discharge, pressure or variations in 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;	NA			It is not medicinal product
(n) precautions to be taken against any special, unusual risks related to the disposal of the device;	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	
'(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;'	NA			No medicinal substance or human blood derivatives
(p) degree of accuracy claimed for devices with a measuring function.	NA			It does not with measuring function
'(q) date of issue or the latest revision of the instructions for use.'	A	EN ISO 15223-1:2016 EN 1041:2008	HC-CE-KZ1-9 Label samples/IFU	

HC-CE-KZ1-4 Risk management report

1. Foreword

This article is prepared for the risk management of Disposable Face Mask. Overall known or foreseeable hazards and the potential causes of each hazard are identified in the article. Furthermore, severity and probability of occurrence of each hazard are estimated. The necessary risk control measures must be taken to the risks which are not acceptable. Residual risk level must be evaluated after risk control measures have been taken.

We have fully considered the requirements of EN ISO 14971 Annex ZA, all risk regardless of their dimension, even negligible risks are considered and balanced, not only non-acceptable risks to be integrated into the overall risk-benefit analysis, all the risks are reduced as far as possible without economic considerations, we have undertaken the risk-benefit analysis for all the individual risk and the overall risk (weighing all risk combined against the benefit) in all case. We have also evaluated if the control actions produce new hazards for our products, and ensure the actions meet the currently knowledge and state of the art.

2.Purposes

The purpose of this risk management is to assist Changzhou Huichun Medical Equipment Co., Ltd. following ENISO14971:2012 in establishing, documenting and maintaining a risk management process for Disposable Face Mask to identify hazards and hazardous conditions, estimate and evaluate the associated risks, control those risks, and continually monitor the effectiveness of the controls put in place throughout the product life cycle.

3.Product Description

3.1 General description

The Disposable Face Mask is composed of face mask body, nasal clamp and mask belt. The inner layer is made of non-woven cloth with Waterproof function, the out layer of face mask body is made of normal non-woven cloth, the middle layer is made of melt spray material, the mask belt is made of elastic material or spandex, the nasal clamp is made of plastically bendable material. The product is non-sterile.

3.2 Packaging

50 pcs per inner box if the customer have no requirements 40 box a carton

3.3 The shelf-life of Disposable Face Mask is 2 years.

3.4 Intended Use

Disposable Face Mask is intended for cover the user’s mouse, nose and underjaw to prevent pollutants exhaled or ejected from oral and nasal cavity under normal medical environment without the risk of body fluid and spray.

3.5 Combination with other devices

No

3.6 Caution

(1) This product is for single use, once open the primary package, use as soon as possible.

(2) The used product shall be treated according to medical waste requirement. Do not use if the package is damaged or expired.

(3) The used product shall be scrapped and destroyed.

(4) Pay attention to the information such as “Pay attention to check the expiry date”, “Do not use if the package is damaged or expired”.

(5)Read the instructions for use before use.

3.7 Contraindications/Side effects

Persons who sensitive to related materials shall be carefully to use this product.

Not use for wound treatment environment

3.8 Instruction for use

(1) Peel the seal of package, take out the face mask, identify the inner side and outer side, pay attention do not contact the white side by hand.

(2) Close to face, hang the belt to two ears, place the mask clamp upon nose, pull the face mask crepe by two hands, press the clamp on nose by middle fingers of two hands, ensure the face mask cover the nose, mouse and underjaw.

4. Qualification of personnel

Persons performing risk management tasks have the knowledge and experience appropriate to the tasks assigned to them. These 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 are showing in 5.2.

5. Risk Management Plan

5.1Scope

This risk management report specifies a process for Changzhou Huichun Medical Equipment Co., Ltd.. to identify the hazards associated with Disposable Face Mask, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of the risk management report are applicable to all stages of the life-cycle of a medical device.

5.2Assignment of responsibilities and authorities

The responsibilities and authorities of the risk team are assigned as followings:

Member	Position	Responsibility
Chen Xia	Director of sales Dept.	Analyze the risk in transpiration and use
Chen Xia	Director of Quality Dept.	Summarize the used analysis, compile risk analysis report
Zheng Xiaobo	General Manager	Implement risk management in the whole production process

5.3 Reference

Refer to

EN ISO 14971:2012Medical devices. Application of risk management to medical devices.

YY/T 0969:2013 Medical face mask-requirements and test method

5.4 Requirements for review of risk management activities

The risk management plan details how and when these management reviews will occur for a specific medical device. The requirements for the review of risk management activities is part of the quality system review requirement.

Stage of life-cycle	Risk management process	Date
Design and development planning	Preliminary Hazard Analysis	2019.12
Design and development inputs	Identification of hazards	2019.12
Design and development outputs	Estimation of the risks for each hazardous situation	2019.12
Design and development verification	Risk evaluation	2019.12
Design and development trial-produce	Risk mitigation and control	2019.12
Design and development validation	Overall residual risk evaluation	2020.1
Product realization	Production/Post-production information	2020.1
Post-production		
Control of design and development changes	Risk evaluation	2020.1
Post-production	Review of Post-production information	2020.1

5.5 Criteria of Risk Evaluation

The criteria for risk acceptability are essential for the ultimate effectiveness of the risk management process.

For each risk we choose appropriate risk acceptability criteria, which are determined according to our policy for determining criteria for risk acceptability and thus are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns.

5.5.1Severity Levels

Severity level of each harm must be estimated (in the form of severity level) by the risk management group.

No.	Severity	Description	Definition
1	Negligible	Inconvenience or temporary discomfort	No complaint or complaints without request.
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention	Feedback of causation analysis and corrective (prevention) measures is required after complaints
3	Serious	Results in injury or impairment requiring professional medical intervention	Cause general compensation
4	Critical	Results in permanent impairment or life-threatening injury	Cause serious compensation
5	Catastrophic	Results in patient death	Cause major compensation results in company insolvency.

5.5.2 Probability of Occurrence

Probability of occurrence of each potential cause must be estimated. In addition, the relative information resources are:

Use of relevant historical data

Prediction of probabilities using analytical or simulation techniques

Use of experimental data

Reliability estimates

Production data

Post-production information

Use of expert judgment

Such level estimations carried out by risk management group can be divided into the following 6 categories.

No	Category	Description
1	Almost impossible	Less than millionth.
2	extremely less	Between hundred thousandth and millionth
3	Seldom	The typical condition is: package of 1 in 1000 cannot be tear open
4	Often	The typical condition is: 1 was found in 100 products
5	Frequent	The typical condition is: occur every 10 products
6	Always	The typical condition is: occurred in each use

5.5.3 Criteria for Risk Acceptability

Probability of occurrence (P)	Severity level (S)				
	1 Negligible	2 Minor	3 Serious	4 Critical	5 Catastrophic
6 Always	AC	NAC	NAC	NAC	NAC
5 Frequent	AC	NAC	NAC	NAC	NAC
4 Often	AC	AC	NAC	NAC	NAC
3 Seldom	AC	AC	AC	NAC	NAC
2 Extremely less	AC	AC	AC	AC	NAC
1Almost impossible	AC	AC	AC	AC	AC

NAC=not acceptable

AC=acceptable

All risks estimated for each harm must be recorded in column “R” of the Appendix B form with range level(AC/NAC) per criteria defined in the table above, and described separately whether control measures are available.

5.6 Verification activities

Per ENISO 14971:2012 the risk management plan should specify two distinct verification activities. The first verification is required to make sure that the risk control measure has been implemented in the final design.

The second verification is required to ensure that the measure as implemented actually reduces the risk. The effectiveness of the risk control measures is verified by a clinical study and the collection of clinical data. The verification activities reference to the plan are showing in the following:

Verification activity	Location in the technical files or Report No.
Performance test	Total performance test report
Biological test	Biocompatibility assessment report
Shelf life verification	Shelf life validation report
Labels	Label and IFU HC-CE-KZ1-9

Instructions for Use	Label and IFU HC-CE-KZ1-9
Supplier audits	Supplier management procedure

5.7 Methods of obtaining relevant post-production information

The methods of obtaining post-production information are part of the established quality management system procedures at Changzhou Huichun Medical Equipment Co., Ltd. which includes: <Advise notice and adverse event report procedure>, <Customer complain management procedure> and <Customer feedback management procedure>.

Changzhou Huichun Medical Equipment Co., Ltd. has established generic procedures to collect information from various sources While a reference to the quality management system procedures can suffice in most cases, any product-specific requirements can be directly added to the risk management plan. The risk management plan includes documentation of decisions, based on a risk analysis, about what sort of post-market surveillance is appropriate for the device, for example, whether reactive surveillance is adequate or whether proactive studies are needed. Details of clinical studies envisaged should be specified.

6. Risk Analysis

6.1 Risk Analysis Process

Risk analysis is performed for Disposable Face Mask as described in 6.2 to 6.4. It includes intended use and identification of characteristics related to the safety of the medical device, identification of hazards and estimation of the risks for each hazardous situation. The implementation of the planned risk analysis activities and the results of the risk analysis are recorded in the risk management file.

Similar medical device information is used in the process and between Disposable Face Mask and similar medical device whether these introduce new hazards or significant differences in outputs, characteristics, performance or results.

In addition to the records required in 6.2 to 6.4, the documentation of the conduct and results of the risk analysis include the following.

a) Description and identification of Disposable Face Mask

Refer to section 3

b) Identification of the persons and organization who carried out the risk analysis

c) Scope and date of the risk analysis

The risk management report includes all stages of the life-cycle of a medical device including verification and evaluation process.

6.2 Intended Use and identification of Characteristics Related to the Safety of the Medical Device

We document the intended use and reasonably foreseeable misuse for Disposable Face Mask. Those qualitative and quantitative characteristics that could affect the safety of Disposable Face Mask are identified and documented in Appendix A. Identification of Characteristics Related to the Safety of Disposable Face Mask.

6.3 Identification of Hazards

According to the experience with the same and similar types of device, publications and other available sources, the documentation on known and foreseeable hazards associated with Disposable Face Mask in both normal and fault conditions are compiled in the Appendix B: The detailes of implementation of risk control measure(s).

6.4 Estimation of the Risks for Each Hazardous Situation

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation have been considered and the resulting hazardous situations have been recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

7. Risk Evaluation

For each identified hazardous situation, we used the criteria defined in the risk management plan to evaluate each harm. Results of the risk evaluation are recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

8. Risk Control

8.1 Risk Reduction

When risk reduction is required, risk control option analysis, implementation of risk control measures, residual risk evaluation, risk/benefit analysis, risk arising from risk control measures, and completeness of risk control activities are performed.

8.2 Risk Control Opting Analysis

Appropriate risk control measures are identified for reducing the risks to an acceptable level. The following risk control options are used in the priority order listed:

b) Protective measures in the medical device itself or in the manufacturing process;

c) Information for safety.

The risk control measures selected are recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

8.3 Implementation of Risk Control Measures

The risk control measures selected are implemented and the implementation of each risk control measure is verified. The verification is recorded in the risk management file. The effectiveness of the risk control measures is verified and the results are recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

8.4 Residual Risk Evaluation

After the risk control measures are applied, any residual risk will be evaluated using the criteria defined in the risk management plan. The results of the evaluation are recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

The residual risks are judged acceptable using these criteria and included in the accompanying documents in order to disclose those residual risks.

8.5 Risk/Benefit Analysis

The residual risk is judged acceptable using the criteria established in the risk management plan and risks are outweighed by the benefits. Necessary information is decided for safety to disclose the residual risk. The results of the evaluation are recorded in the risk management file.

8.6 Risk Arising from Control Measures

There is no new risk arising from risk control measures. The results are recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

8.7 Completeness of Risk Control

The risks from all identified hazardous situations have been considered. The results of this activity are recorded in the risk management file in Appendix B: The details of implementation of risk control measure(s).

9. Evaluation of Overall Residual Risk Acceptability

After all risk control measures have been implemented and verified, the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan.

Overall residual risk evaluation is the point where residual risk is viewed from broad perspective. Overall residual risk evaluation is performed by persons with the knowledge, experience, and authority to perform such tasks described in the risk management plan.

It involves application specialists with knowledge of and experience with the medical device. Review of warnings and operating instructions were selected to disclose overall residual risk. For details please refer to Appendix C: Evaluation of Overall Residual Risk Acceptability.

10. Production/Post-Production Information

A system is establishing, document and maintain to collect and review information about the medical device or similar devices in the production and the post-production phases. For details please refer to <Advise notice and adverse event report procedure>, <Customer complain management procedure> and <Customer feedback management procedure> at Changzhou Huichun Medical Equipment Co., Ltd.

When establishing a system to collect and review information about the medical device, the following things are considered:

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, and

b) New or revised standards; and

c) Design change; and

d) Change of material supplier or manufacture process.

The system can also collect and review publicly available information about similar medical devices on the market. The information will be evaluated for possible relevance to safety,

especially the following:

----if previously unrecognized hazards or hazardous situations are present or;

----if the estimated risks arising from a hazardous situation are no longer acceptable.

If any of the above conditions occur:

1) The impact on previously implemented risk management activities shall be evaluated and shall be fed back as an input to the risk management process and;

2) A review of the risk management file for the medical device shall be conducted; if there is a potential that the residual risks or its acceptability has changed, the impact on previously

implemented risk control measures shall be evaluated. The results of this evaluation will be recorded in the risk management file.

Production and post-production information shall be collected, monitored and analyzed as per company’s quality system procedures/work instructions and recorded in the appendix D: Production and post-production information

11. Annual Risk Management

Risk management will be review annually, the following information will be considered especially:

No.	Information	Department
1	New or revised standards	Quality
2	Adverse event	Quality
3	Notice/Recall	Quality
4	Feedback or Customer complain	Sales & Quality
5	Internal audit	Quality
6	Monitoring and measurement of processes	Quality
7	Monitoring and measurement of product	Quality
8	Change of design or manufacture process	Technology & Quality

12. Results and Conclusion

The implementing of the risk management process for Disposable Face Mask is completely according to EN ISO 14971:2012, according to structure, it can divide into size Small and size large, according to the contact body mode is divided into surface contact device. It's assembled and packaged in 100000 class clean room. Disposable Face Mask has more benefits like simple production and convenient use. The advantages of using Disposable Face Mask are obvious and its benefit is much greater than its risk. The residual risk and overall residual risk of the Disposable Face Mask are acceptable. Therefor the overall benefits overweigh the risks.

Annex A: Identification of qualitative and quantitative characteristics:(acc. to ENISO14971:2012 Annex C)

Question No	Question	Characteristics Determination	Possible Risks	Hazard Identification
C.2.1	What is the intended use and how is the medical device to used?	Disposable Face Mask is intended for cover the user's mouse, nose and underjaw to prevent pollutants exhaled or ejected from oral and nasal cavity under normal medical environment without the risk of body fluid and spray. Use method: (1) Peel the seal of package, take out the face mask, identify the inner side and outer side, pay attention do not contact the white side by hand. (2) Close to face, hang the belt to two ears, place the mask clamp upon nose, pull the face mask crepe by two hands, press the clamp on nose by middle fingers of two hands, ensure the face mask cover the nose, mouse and underjaw.	Hazards related to the use of the device and contributory factors	H4.1 H4.2 H4.3 H4.4 H4.5 H4.7 H4.8 H4.9 H4.10
C.2.2	Is the medical device intended to be implanted?	No		
C.2.3	Is the medical	Yes. Contact face surface	Biological	H2.2

	device intended to be in contact with the patient or other persons?		hazards	
C.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	The Disposable Face Mask is composed of face mask body, nasal clamp and mask belt. The inner layer and out layer of face mask body is made of non-woven cloth, the middle layer is made of melt spray material, the mask belt is made of elastic material, the nasal clamp is made of plastically bendable Material	Biological hazards	H2.2
			Hazards related to the use of the device and contributory factors	H4.3
C.2.5	Is energy delivered to or extracted from the patient?	No.	/	/
C.2.6	Are substances delivered to or extracted from the patient?	No.	/	/
C.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No.	/	/
C.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No.	/	/
C.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	No.	/	/
C.2.10	Is the medical device intended to modify the patient environment?	No.	/	/
C.2.11	Are measurements taken? Factors that should be considered include the variables	No.	/	/

	measured and the accuracy and the precision of the measurement results.			
C.2.12	Is the medical device interpretative?	No.	/	/
C.2.13	Is the medical device intended for use in conjunction with other medical devices medicines or other medical technologies?	No.	/	/
C.2.14	Are there unwanted outputs of energy or substances?	No.	/	/
C.2.15	Is the medical device susceptible to environmental influences?	Yes, Rough handling during transportation may cause breakage of single package and breakage of the package. And the raw materials of the product are medical materials, the packaging materials have been verified by simulated transport, the temperature and humidity are required during storage. If the product is produced in a non-cleanliness-controlled environment, the bioburden will be too high	Biological hazards	/
			Environmental hazards and contributory factors	H3.7
			Hazards arising from functional failure, maintenance and ageing	H6.4
			Biological hazards	/
C.2.16	Does the medical device influence the environment?	No.	/	/
C.2.17	Are there essential consumables or accessories with the medical device?	No.	/	/
C.2.18	Is maintenance or calibration necessary?	No.	/	/
C.2.19	Does the medical device contain software?	No.	/	/
C.2.20	Does the medical device have a restricted shelf-life?	Yes, the aging test report support 2 years shelf-life.	Hazards related to the use of the device and contributory	H4.9

			factors	
			Hazards arising from functional failure, storage and ageing	H6.9
C.2.21	Are there any delayed or long-term use effects?	No.		
C.2.22	To what mechanical forces will the medical device be subjected?	No.	/	/
C.2.23	What determines the lifetime of the medical device?	Yes, Product materials, packaging materials determine the life of the product	Biological hazards	/
			Hazards arising from functional failure, storage and ageing	H6.4 H6.9
C.2.24	Is the medical device intended for single use?	Yes, it is for single use.	Hazards related to the use of the device and contributory factors	H4.10
C.2.25	Is safe decommissioning or disposal of the medical device necessary?	Yes, destroyed as medical waste after use. The device does not produce toxic substances and the material does not need to be recycled.	Hazards related to the use of the device and contributory factors	H4.10
C.2.26	Does installation or use of the medical device require special training or special skills?	Yes, the product must be used by trained medical professionals or normal person.	Hazards related to the use of the device and contributory factors	H4.7
C.2.27	How will information for safe use be provided?	Yes, refer to user manual or device label. Use the device by the skilled/trained personnel.	Hazards related to the use of the device and contributory factors	H4.1 H4.2 H4.3 H4.4 H4.5 H4.7 H4.8 H4.9 H4.10
C.2.28	Will new manufacturing processes need to be established or introduced?	No.	/	/
C.2.29	Is successful application of the medical device critically dependent on human factors such as the user interface?	No.	/	/
C.2.29.1	Can the user interface design	No.	/	/

	features contribute to use error?			
C.2.29.2	Is the medical device used in an environment where distractions can cause use error?	No.	/	/
C.2.29.3	Does the medical device have connecting parts or accessories?	No.	/	/
C.2.29.4	Does the medical device have a control interface?	No	/	/
C.2.29.5	Does the medical device display information?	No	/	/
C.2.29.6	Is the medical device controlled by a menu?	No	/	/
C.2.29.7	Will the medical device be used by persons with special needs?	Yes, The product used by the person in normal medical environment, not used in ICU and wound surgical operation	Hazards related to the use of the device and contributory factors	H4.1 H4.2 H4.3 H4.4 H4.5 H4.7 H4.8 H4.9 H4.10
C.2.29.8	Can the user interface be used to initiate user actions?	No.	/	/
C.2.30	Does the medical device use an alarm system?	No.	/	/
C.2.31	In what way(s) might the medical device be deliberately misused?	No.	/	/
C.2.32	Does the medical device hold data critical to patient care?	No.	/	/
C.2.33	Is the medical device intended to be mobile or portable?	No.	/	/
C.2.34	Does the use of the medical device depend on essential	Yes, the essential performance determines the safety and effectiveness of the product	Hazards arising from functional failure, storage and ageing	H6.7 H6.8 H6.10

	performance?			
C.2.35	If components of the medical device are securely mounted for the expected service lifetime of the medical device?	No.	/	/
C.2.36	What multi-purpose outputs (e.g. low-intensity and high-intensity) for different treatments are provided for the medical device?	No.	/	/

Annex B: The details of implementation of risk control measure(s)

No.	Hazard		Risk Evaluation			Risk Reduction Measure	Evidence	Risk Evaluation After Adopting Measures			NH	ALOR
	General	Identify hazards	S	P	RL			S	P	RL		
1. Energy Hazards												
H1.1	Electricity	No										
H1.2	Heat	No										
H1.3	Mechanical force	No										
H1.4	Ionizing radiation	No										
H1.5	Non-ionizing radiation	No										
H1.6	Electromagnetic fields	No										
H1.7	Moving parts	No										
H1.8	Suspended masses	No										
H1.9	Patient support device failure	No										
H1.10	Pressure (vessel rupture)	No										
H1.11	Acoustic pressure	No										
H1.12	Vibration	No										
H1.13	Magnetic fields (e.g. MRI)	No										
2. Biological hazards												
H2.1	Bio-contamination	No										
H2.2	Bio-incompatibility	If the material	4	3	NAC	1. Make the key raw	Biocompatibility test	4	1	AC	N	Y

		itself is biological incompatibility, the device will harm to patient.				material and purchased parts standards, raw materials and purchased parts should meet the medical requirements. 2.perform Biocompatibility evaluation for final product 3. Strictly implement the procurement control procedures	report of non-woven cloth material Biocompatibility evaluation of final product Daily process control					
H2.3	Bio-contamination	No											
H2.4	Chemical Toxicity	No											
H2.5	Particle contamination or Bacterial endotoxin	No											
H2.6	Mutagenicity	No											
H2.7	Oncogenicity	No											
H2.8	Teratogenicity	No											
H2.9	Carcinogenicity	No											
H2.10	Re-and/or cross-infection	No											
H2.11	Inability to maintain hygienic safety	No											
H2.12	Degradation	No											
H2.13	Incorrect formulation(chemical composition)	No											
3. Environmental hazards and contributory factors													
H3.7	Storage or operation outside prescribed environmental conditions	The storage environment will cause product aging	3	4	NAC	It is declared the storage condition in the Instruction for Use.	Instruction for Use	3	1	AC	N	Y
H3.8	Incompatibility with other devices	No											
H3.9	Accidental	No											

	mechanical damage												
H3.10	Contamination due to waste products and/or device disposal	No											
H3.11	Under least favourable working condition	No											
H3.12	Mechanical strength and resistance to heat	No											
H3.13	Environment pollution	No											

4. Hazards related to the use of the device and contributory factors												
H4.1	Inadequate labeling	Inadequate labeling will cause incorrect use.	3	4	NAC	It is declared the usage in the “Instruction for Use”	Instruction for Use	3	2	AC	N	Y
H4.2	Inadequate Operating Instructions	Inadequate operating will cause the medical device cannot achieve its intended use.	3	4	NAC	Usage and attention of using are elaborated 1n the “Instruction for Use”	Instruction for Use.	3	2	AC	N	Y
H4.3	Inadequate Specification of accessories	Inadequate Specification of product may cause it cannot match with face of user’s	4	3	NAC	The product use method is indicated in “Instruction for Use”, and the type and size is control at production and inspection process	Instruction for Use. Production inspection specification	4	1	AC	N	Y
H4.4	Inadequate Specification of Pre-use checks	The product is damaged and is not checked, and the product cannot be used. Error information or inadequate information of attentions	3	4	NAC	Check the product before use and attentions are elaborated in the “Instruction for Use”	Instruction for Use.	3	1	AC	N	Y

		will cause misusing.										
H4.5	Overcomplicated Operating instructions	Overcomplicated operating Instructions, Product is used incorrectly	3	4	NAC	Instructions for use in “Instruction for Use” are simple and easy to understand	Instruction for Use.	3	1	AC	N	Y
H4.6	Inadequate specification of service and maintenance	No										
H4.7	Use by unskilled/untrained personnel	Will cause the medical device cannot achieve its intended use or harm the user and the patient.	3	4	NAC	The warning for the device must be used by the medical professionals	Instruction for Use.	3	1	AC	N	Y
H4.8	Reasonably Foreseeable misuse	Used wrongly for contraindications and harm the user and the patient.	3	4	NAC	contraindications are elaborated in the “Instruction for Use”	Instruction for Use.	3	1	AC	N	Y
H4.9	Insufficient warning of side effects and cannot use beyond the date of expiry	Used wrongly and used the product beyond the date of expiry harm the user and the patient.	2	2	4	warnings are elaborated in the “Instruction for Use”	Instruction for Use.	2	1	AC	N	Y
H4.10	Inadequate warning of hazards likely with re-use of single use devices.	Failing to destroy the product after use and be re-used, harm the user and the patient.	2	2	4	The warning of only single use is elaborated in the “Instruction for Use” and label.	Instruction for Use. Label	2	1	AC	N	Y
H4.11	Incorrect measurement and other metrological aspects.	No										
H4.12	Incompatibility with consumables/accessories/other devices	No										
H4.13	Sharp edges or points	No										
5. **Inappropriate, inadequate or over-complicated user interface (man/machine communication)**												
H5.1	Mistakes and judgement errors	No										
H5.2	Lapses and cognitive recall errors	No										
H5.3	Slips and blunders (mental or physical)	No										

H5.4	Violation or abbreviation of instructions, procedures, etc.,	No										
H5.5	Complex or confusing control system	No										
H5.6	Ambiguous or unclear device state	No										
H5.7	Ambiguous or unclear presentation of settings, measurements or other information	No										
H5.8	Mispresentation of results	No										
H5.9	Insufficient visibility, audibility or tactility	No										
H5.10	Poor mapping of controls to action, or of displayed information to actual state.	No										
H5.11	Controversial modes or mappings as compared to existing equipment.	No										
6. **Hazards arising from functional failure, maintenance and ageing**												
H6.1	Erroneous data transfer.	No										
H6.2	Lack of, or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	No										
H6.3	Inadequate maintenance	No										
H6.4	Inadequate packaging (contamination and/or deterioration of the device)	It may cause the medical device damage and, cannot achieve its intended use.	4	3	NAC	Select suitable packing materials and packing forms,	Incoming inspection specification	4	1	AC	N	Y
H6.5	Re-use and/or Improper re-use	No										
H6.6	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	Reuse	4	3	NAC	Clear identified in label and IFU the device is for single use	Instruction for Use. Label	4	1	AC	N	Y
H6.7	Poor connectivity firmness of face mask tie	Failure in wearing	4	3	NAC	1. The joint strength between tie and face	1.Product standards and	4	1	AC	N	Y

						mask body should bear not less than 10N quiet tensile force, 2.Establish process inspection regulations and standards, and carry out inspection	enterprise inspection regulations 2.Test report of finish products					
H6.8	Broken or hole in the device	It cannot protect the user	4	3	NAC	Check the appearance in daily control and inspection process	Inspection specification and record	4	1	AC	N	Y
H6.9	BFE is not get the intended purpose	It may cause use infection	4	4	NAC	We have pass the BFE test, and fixed raw material supplier, BFE is not less than 95%	Full performance test report and product test inspection specification	4	1	AC	N	Y
H6.10	Airflow resistance is not getting the intended purpose	.it may caused user suffocate	4	3	NAC	We have passed the airflow resistance test of product, and the airflow resistance is not high than49KP/CM2	Full performance test report	4	1	AC	N	Y
7. **Hazards related to the clinical use**												
H7.1	The improper use of the product by the User	It may result in treatment delay or user infection	4	3	NAC	Training Users on How to Use Products Correctly	Operating manual User training records	4	1	AC	N	Y
H7.2	The User cannot make the right use	It may result the product cannot fulfil the user's face	4	3	NAC	Training Users on How to Use Products Correctly	Operating manual User training records	4	1	AC	N	Y

Appendix C: Evaluation of Overall Residual Risk Acceptability

C1. General

After all risk control measures have been implemented and verified, the overall residual risk posed by Disposable Face Mask are acceptable using the criteria defined in the risk management plan. Overall residual risk evaluation is viewed from a broad perspective and performed by persons with the knowledge, experience, and authority to perform such tasks. It is involving application specialists with knowledge of and experience with Disposable Face Mask.

Review for conflicting requirements, review of warnings, review of the operating instructions is chose for evaluating overall residual risk.

The necessary information is included in the Labels and Instructions for Use to disclose the overall residual risk.

C2. Information for safety

The information for safety and effectively is developed to provide to patients, users and others who will contact the product. It is provided in labels and instructions for use which including an explanation of risk, the consequences of exposure and what should be done or avoided to prevent harm. In developing the information, the following have been considering:

---the level of priority appropriate to classify an action (warning, caution, etc.);
---the level or detail of information needed;
---the location for the information for safety (e.g. a storage condition);
---the wording or pictures to be used to ensure clarity and understandability;
---the immediate recipients (e.g. users, service personnel, patients);
---the appropriate media for providing the information, (e.g. labels and instructions for use);
---regulatory requirement.

C3. Disclosure of residual risks

When developing the disclosure of overall residual risks, the indication, instructions for use, contraindication, warning, storage and presentations are identified to be communicated and the medical staffer is directed in order to inform, motivate and enable the user to use the device safely and effectively.

According to examine the residual risks what should be disclosed is determined. The followings are considered:

---the level or detail needed;
---the wording to be used to ensure clarity and understandability;
---the immediate recipients (e.g. users, service personnel, installers, patients);
---the means/media to be used (e.g. labels and instructions for use on paper in package).

Appendix D: Production and post-production information

Post-market surveillance records for Disposable Face Mask

Marketing period: /

Sales figures: 0 pcs

Reportable Events & FSCAs: Details are listed in below tables:

Time	Customer complaints	Qty	Harm to the user/patients
2020.01—2020.3	0	0	0

Year	Sales volume per year	Complaints	Involved batch
2020.01—2020.3	0	0	/

Year	Complaints	Cause analysis &CAPAs
2020.01—2020.3	0	0

Conclusion: Until now, this product hasn't sold in the European and the other countries. We will collect and analysis the PMS data in the following years, record customer complaint happened and make CAPA, once customer complaints and adverse events are related to the safety and effectiveness of the product, risk evaluation and measures need to be taken to implement them, and this risk management report shall be updated.

HC-CE-KZ1-5 Design and manufacture information

1. Product structure

The Disposable Face Mask is composed of face mask body, nasal clamp and mask belt. The inner layer is made of non-woven cloth with Waterproof function, the out layer of face mask body is made of normal non-woven cloth, the middle layer is made of melt spray material, the mask belt is made of elastic material or spandex, the nasal clamp is made of plastically bendable material. The product is non-sterile.

2. Product type, size and material information

2.1 Type and size

Type	Dimension (cm)	color	nasal clamp length (cm)	Ear tie length (cm)
G	17.5±0.3×9.5 ±0.3	white (W) /blue (B)	≥8.0	16.0±0.5
X				35.0±0.5

2.2 Material

Components	Material	supplier
Inner layer	Non-woven	Guangdong Feifan Material Technique Company
Out layer	Non-woven	Guangdong Feifan Material Technique Company
Middle layer	spray material	Dongli Synthetic fiber(Nantong) Company
tie	elastic material	
Nasal clamp	plastically bendable material (PVC coated galvanized iron strip)	

3. Performances

The product is complying with requirements of YY/T 0969-2013 <Disposable Face Mask>. Main performance:

(1) Appearance smooth and clean, figure is fit, surface has no damage or dirty.

(2) The face mask covered on face can cover the nose, mouse and underjaw well.

(3) There is nasal clamp on face mask, it has plasticity, the nasal clamp length does not less than 8.0cm.

(4) The face mask is convenient to use, the minimum breaking load of mask body and mask belt is not less than 10N.

(5) The bacteria filtration rate is not less than 95%.

(6) The air exchange pressure difference of two sides of face mask △p is not more than 49Pa.

(7) The non-sterile type face mask bioburden is ≤100CFU/g.

3. Production flow chart

Nonwoven cloth, melt spray material, mask belt, the nasal clamp is made of plastically bendable material → Mask body press piece → Weld the belt → primary package → seal → Outer package → Finished product.

5. Quality Control

5.1 In-coming inspection

5.1.1 Quality department performs sampling inspection or verification according to <Raw material, purchased components inspection specification> and provides inspection report.

5.1.2 Frequency: Each batch.

5.2 In-process inspection

5.2.1 Quality department and production department performs in-process inspection respectively according to requirement of <In-process inspection specification>.

5.2.2 Frequency: Each batch.

5.3 Finished goods inspection

5.3.1 Quality department performs finished goods inspection according to <Final inspection specification of Disposable Face Mask> and provides inspection report.

5.3.2 Frequency: Each batch.

5.4 Type test

5.4.1 According to YY/T 0969:2013 Disposable Face Mask performed test by lab .

5.4.2 Frequency: performed if the raw material and product flowchart change.

6. Environment control description

6.1 Production of Disposable Face Mask of face mask body making, mask tie welding and single package are completed in 100000 class clean room.

6.2 Control requirement of 100000 class clean room:

6.3. Environment control description

6.4 Production of Disposable Face Mask of face mask body making, mask tie welding and single package are completed in 100000 class clean room of ISO class 8 according to ENISO14644-1:2015 (100000 class clean room according to YY0033-2010)

6.5 Control requirement of 100000 class clean room:

Monitoring item		Requirement	According to	Frequency
Temperature, ℃		18～28	ENISO14644-1: 2015 and ENISO14644-2 :2000 (Refer to YY0033:2000)	Once a shift
Related humidity, %		45～65		Once a shift
Air changing times, times/hour		≥15		Once a month
Wind speed, m/s		——		Once a month
Static pressure difference, Pa		Between clean rooms / areas with different cleanliness levels Between clean room / area and unclean room / area ≥5		Once a month
		Between clean room / area and outdoor ≥10		
Dust particles, pcs/m3	≥0.5μm	≤3500000		Once a quarter
	≥5μm	≤2000		
Air-borne microorganism in air, cfu/ m^3		500		Once a quarter
Sedimented microorganism, cfu/plate		≤10		Once a week

6.6 Cleanliness requirement comparison table between 100000 class in YY0033 and class 8 in ENISO14644-1

Classification	Maximum concentration limits (particles/m3 of air)		
	0.5um	1um	5um
100000 class according YY0033	3500000	20000	
ISO class 8 according to ENISO14644-1	3520000	832000	29300
Results: Clean requirements of 100000 class according YY0033 is stricter than ISO class 8 according to ENISO14644-1, so our company adopt control method according to 100000 class requirements specified in YY0033.			

7. Identification and traceability

The traceability may be realized by following method:

Product label → sales list → Finished goods leaving warehouse record → Finished goods inspection record → production record → incoming inspection record → raw material

HC-CE-KZ1-6 Pre-clinical study

In order to get the evidence that Disposable Face Mask meet the requirements of MDD and in particular the applicable Essential requirements, we perform some verification and validation tests and/or studies for the products.

1. Biocompatibility test

1.1 According to requirements of ENISO10993-1:2018 Table A.1, our product contact human body skin, contact time is not more than 24h, we tested the biocompatibility concerning three items:
Cytotoxicity, Irritation and Sensitization.

(1) Cytotoxicity test

a) In this test, the cell culture technology was adopted; the purpose is to test the effect of device, material and / or its extraction fluid on cell such as cell lysis (cell death) and other cell growth resistance.

b) According to above-mentioned test method, a certain volume of extraction fluid was added into L-929 cell fluid, after incubation, analyze the growth and reproduction of cell and evaluate the potential toxicity of sample on cell.

(2) Irritation test

a) In this test, a suitable model was adopted, test the irritation effect of material and /or its extraction fluid on the corresponding part of skin. The test duration of irritation effect with device, material and its leachable substrate shall be applicable with the contact duration with tissue (such as skin).

b) According to above-mentioned test method, a certain volume of extraction fluid of product was injected into rabbit, observe the local skin reaction, and evaluate the irritation effect of sample on contact tissue.

(3) Sensitization test

In this test, a certain volume of sample solution was used to contact with guinea pig to test the potential contacting skin abnormality reaction caused by sample solution.

1.2 Sample selection:

According to the actual situation of our company, we choose materials of non-woven to analyze the biocompatibility.

Our non-woven cloth supplier has perform Cytotoxicity test, Irritation test and Sensitization test.It can meet our requirement.

1.3 Conclusion:

The above-mentioned tests showed the product has no potential cytotoxicity, no skin irritation, no sensitivity reaction, so the biocompatibility of our Disposable Face Mask is passed.

Annex:
Cytotoxicity test report
Sensitization test report
Irritation test report

2. Full performance test

2.1 Our company conducted sampling inspection batch by batch according to Product standard of Disposable Face Mask and Finally inspection specification of Disposable Face Mask, the test results refer to our final product inspection record.

2.2 Full performance test are performed

We have performed full performance test according to YY/T 0969:2013 standard and compliance with standard requirements.

Annex:

Product performance test report

HC-CE-KZ1-7 Clinical evaluation reports

1. Summary

1.1 General principles

This clinical discussion is developed to provide a comprehensive analysis of available pre and post market clinical data relevant to the intended use of Disposable Face Mask, to ensure that there is sufficient evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's instructions for use. Clinical evaluation is an ongoing process conducted throughout the life cycle of a medical device.

In exceptional cases where an instruction for use is not required, the collection, appraisal, and analysis are conducted taking into account generally recognized modalities of use.

The requirements for clinical evaluation apply to all classes of medical devices. The evaluation should be appropriate to the device under evaluation, its specific properties, and its intended purpose.

Benefits and risks should be specified, e.g. as to their nature, probability, extent, duration and use frequency. Core issues are the proper determination of the benefit/risk profile in the intended target groups and medical indications, and demonstration of acceptability of that profile based on current knowledge/ the state of the art in the medical fields concerned.

Clinical evaluation is first performed during the conformity assessment process leading to the marketing of a medical device and then repeated periodically as new clinical safety and performance information about the device is obtained during its use. This information is fed into the ongoing risk analysis and may result in changes to the Instructions for Use.

1.2 Goals and Objectives

This clinical evaluation is aimed to:

Identify and discuss the literature data on Disposable Face Mask, aimed for a similar indication that support the safety and performance claims. Clinical evaluation is the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device；

Present the clinical safety and effectiveness of Disposable Face Mask and demonstrate the conformity of the product to Essential Requirements of Medical Device Directive, especially Section 1, 3, 6 of Annex I according to MDD 93/42/EEC.

We reviewed below several aspects, the compliance to harmonized standards, intended applications/indications/claims, substantially equivalence comparison to the predicate device, and the evaluation of relevant scientific literature, the clinical data analysis of data and appraisal.

1.3 Benefit/risk analysis for device

We have conduct risk management in the whole lifetime of product according to EN ISO 14971:2012, details see risk management report. The complete risk management report also shows the risk of Disposable Face Mask are acceptable about the intended application. Moreover, equivalent products have been on the market in Europe with CE mark, USA cleared by FDA and China cleared by CFDA for many years and products have received few severe adverse event reports so far, this means the products' performance and safety is very good.

The risk assessment of Disposable Face Mask have already considered all the known risks and foreseeable risks related to design, production, storage and intended use, the risk management plan has been properly implemented; comprehensive residual risk is acceptable; for the appropriate method to obtain information related to production and post production. All the measurements and validations referred in this report has been adequately recorded in the Risk Management Report. The Disposable Face Mask have been safety and effectively implemented its intended use. We did not find the extra risks related to the design, production, storage and intended use. All remaining risks of Disposable Face Mask is acceptable, and risk criteria, and benefits more than its risk.

1.4 Summary for the acceptability under the state of the art in medical fields

The Disposable Face Mask is composed of face mask body, nasal clamp and mask belt. The inner layer and out layer of face mask body is made of non-woven cloth, the middle layer is made of melt spray material, the mask belt is made of elastic material, the nasal clamp is made of plastically bendable Material, the final product shall meet the requirement of YY/T 0969:2013

2. Scope of the clinical evaluation

2.1 Scope

This report aims to determine the safety and performance in the application of Disposable Face Mask.

2.2Device description

2.2.1 Name: Disposable Face Mask

2.2.2 Types: small and large

2.2.3 Picture: see Part 2.

2.2.4 Dimension:

Type	Dimension （cm）	color	nasal clamp length（cm）	Ear tie length （cm）
G	17.5±0.3×9.5±0.3	white（W） /blue（B）	≥8.0	16.0±0.5
X				35.0±0.5

2.2.5 Main components of the device:

The Disposable Face Mask is composed of face mask body, nasal clamp and mask belt. The inner layer is made of non-woven cloth with Waterproof function, the out layer of face mask body is made of normal non-woven cloth, the middle layer is made of melt spray material, the mask belt is made of elastic material or spandex, the nasal clamp is made of plastically bendable material. The product is non-sterile

2.2.6Device group to which the device belongs: non-woven device

2.2.7Device state: CE marked

2.2.8 Sales market: Our product mainly sale to USA, China and Africa

2.2.9 Sterilization method: not sterile

2.3Intended purpose of the device

Items	Details
Intended use/ Exact medical indications	Disposable Face Mask is intended for cover the user’s mouse, nose and underjaw to prevent pollutants exhaled or ejected from oral and nasal cavity under normal medical environment without the risk of body fluid and spray.

<table>
<tr><td>Disease or condition</td><td>Normal medical environment</td></tr>
<tr><td>Patient populations</td><td>Patients with not wound</td></tr>
<tr><td>Intended user</td><td>The product shall be used only by the professional who is thoroughly knowledgeable in the product’s usage method and clinical application.
Information of intended user is detailed in IFU, please refer to “Instructions for use”</td></tr>
<tr><td>Contacted by the device</td><td>According to ENISO10993-1:2018, Disposable Face Mask is the surface medical device that contact face skin, contact duration is ≤24 h, it must conform to the of ENISO10993-5:2009, ENISO10993-7:2008, ENISO10993-10:2010 , The maternal of product has pass the biocompatibility test to conform to the Biocompatibility requirements, detail sees the test report.</td></tr>
<tr><td>Duration</td><td>≤24 h</td></tr>
<tr><td>Repeat applications</td><td>For single use</td></tr>
<tr><td>Principles of operation</td><td>(1) Peel the seal of package, take out the face mask, identify the inner side and outer side, pay attention do not contact the white side by hand.
(2) Close to face, hang the belt to two ears, place the mask clamp upon nose, pull the face mask crepe by two hands, press the clamp on nose by middle fingers of two hands, ensure the face mask cover the nose, mouse and underjaw.</td></tr>
<tr><td>Contraindications</td><td>Persons who sensitive to related materials shall be carefully to use this product.
Not use for wound treatment environment
Not use in ICU and wound surgical operation</td></tr>
<tr><td>Precautions</td><td>(1) This product is for single use, once open the primary package, use as soon as possible.
(2) The used product shall be treated according to medical waste requirement. Do not use if the package is damaged or expired.
(3) The used product shall be scrapped and destroyed.
(4) Pay attention to the information such as “Pay attention to check the expiry date”, “Do not use if the package is damaged or expired”.
(5)Read the instructions for use before use.</td></tr>
<tr><td>Materials</td><td><table><tr><td>Components</td><td>Material</td></tr><tr><td>Inner layer</td><td>Non-woven with Waterproof function</td></tr><tr><td>Out layer</td><td>Non-woven</td></tr><tr><td>Middle layer</td><td>spray material</td></tr><tr><td>tie</td><td>elastic material or spandex</td></tr><tr><td>Nasal clamp</td><td>plastically bendable material</td></tr></table></td></tr>
<tr><td>Performance</td><td>The product is complying with requirements of YY/T 0969-2013 <Disposable Face Mask>. Main performance:
(1) Appearance smooth and clean, figure is fit, surface has no damage or dirty.
(2) The face mask covered on face can cover the nose, mouse and underjaw well.
(3) There is nasal clamp on face mask, it has plasticity, the nasal clamp length does not less than 8.0cm.
(4) The face mask is convenient to use, the minimum breaking load of mask body and mask belt is not less than 10N.
(5) The bacteria filtration rate is not less than 95%.
(6) The air exchange pressure difference of two sides of face mask △p is not more than 49Pa.
(7) The non-sterile type face mask bioburden is ≤100CFU/g.</td></tr>
<tr><td>Medicinal substance</td><td>There is no medicinal substance in the device.</td></tr>
</table>

2.4 Clinical performance:

When Disposable Face Mask is used for covering the user’s mouse, nose and underjaw to prevent pollutants exhaled or ejected from oral and nasal cavity under normal medical environment without the

risk of body fluid and spray, it contacts with user face skin.

2.5 Side-effect: no clear side-effect.

2.6 label and IFU
Labels and IFU have been established; refer to file of HC-CE-KZ1-9 Version. 1

3. Clinical background, current knowledge, state of the art
We identified and defined the current knowledge/ state of the art, the latest standard for the device is YY/T 0969:2013 Disposable Face Mask-requirement and test method.

4. Device evaluation method
According to Rule 1 of Annex IX in MDD93/42/EEC, the face mask is non-active device contact with human body surface, not sterile, is Class I device. And this is a very normal device in clinical use, so we perform clinical evaluation through product compliance assessment. We have pass full performance test according to YY/T 0969-2013, detail see the test report.

5 Post Market Surveillance (PMS) Request and Determination
The following procedures cover post market surveillance and vigilance reporting:
Refer to the following:

Document Title
Feedback Information Management Procedure
Adverse Event Reporting & Advisory Notices Control Procedure
Corrective and Preventive Action Control Procedure
Vigilance System Control Procedure

Periodical review of the feedback, complaints, vigilance and post market surveillance, etc. is conducted according to the SOP above.
We has established PMS procedure to collect complaints, incidents, adverse events after the product marketed and these data will be evaluated by us and determine whether to conclude change the evaluation of the risk/benefit profile, clinical performance and clinical safety of the device, result in changes to the risk management documents, instructions for use, etc. is still acceptable.
Purpose:
To define the process and frequency of activities for gathering post-market data as an input into clinical evaluations and risk analysis.
Scope:
The scope of this post-market surveillance plan is limited to Disposable Face Mask during the period of the whole shelf-life of the product.
Note: If different PMS inputs cover different periods of time, then this should be clarified in the PMS report. Often a table is ideal to communicate this information.
Responsibilities & Authorities:
The table in the PMS inputs section defines the personnel that are responsible for gathering each type of PMS data for Disposable Face Mask. Each person is responsible for gathering the data, summarizing that data, writing a brief discussion of the data analysis and documenting a conclusion that states whether the data warrants updating the PMS report at this time or to continue gathering data until the

next cycle is completed. If no new clinical data is gathered during the period, then there may be no need to update the clinical evaluation report. If there are no new risks identified and the data suggests that no changes to the current risk analysis are needed, then the risk analysis may not need to be updated either. The recommended frequency for the next summary of data should be indicated in the conclusion as well.

PMS Plan:

The following table identifies the PMS Plan input for Disposable Face Mask.

Item #	Description of Input	Responsible Person	Frequency of Review
1	Information from R&D (may include contract design firm)	Technique manager	At design phase reviews
2	Service data (individual service records and statistical analysis in accordance with ISO 13485:2016 Item 7.5.4)	Sale Manager	Monthly
3	Complaint data (individual complaint records and trend analysis of complaints as per ISO 13485:2016 Item 8.2.2)	Quality manager	Monthly
4	Customer Feedback Surveys	Quality manager	Quarterly
5	Adverse Event Databases (e.g., MAUDE)	Quality manager	Quarterly
6	New & Revised Regulatory Requirements & External Standards	Technique manager	Management Review Output
7	Drug-related information (if applicable)	Quality manager	Quarterly
8	Own-Brand Labeled PMS (if applicable)	Quality manager	Quarterly
9	Sales force, Distributor & Tradeshow Feedback	Sales	Quarterly

Data Summary:

Each person responsible for gathering PMS data shall summarize the data on the frequency identified in the table above. If there is no new data to report, this should be stated in the summary. If there is a large amount of similar data, it is acceptable to present a statistical analysis of that data (refer to Statistical Techniques control procedure).

Discussion of Data:

If the data gathered is similar to previous data gathered, then this should be stated in the discussion. If there is new data, the severity of harm caused by device malfunction changes or if the frequency of incidents changes this should be stated in the discussion. A separate discussion of data from each input source is recommended. In the periodic PMS report, it should be stated which input sources identified significant new data or changes in the data trends.

Conclusions:

The conclusion of each summary report from each PMS input should state if a PMS report is recommended based upon the inputs or if it is acceptable to continue to gather data without generating a periodic PMS report. Any new risks, changes to risks or changes to frequency of occurrences should be noted and should trigger either an update to the clinical evaluation report, the risk analysis or both.

The recommended time for conducting the next review of PMS data from each source should be specified in the conclusions.

Training of personnel:

All personnel that are involved in the review of PMS data shall be trained on the following procedures:

Risk Management

Post-Market Surveillance

Clinical Evaluation Procedure

Documents & Records:

The PMS plan for each product family shall be assigned a controlled document number and changes to the plan shall be documented as a controlled revision in accordance with documents control.The summary reports for each PMS data source and the periodic summary reports of PMS data shall be controlled quality system records that reference the PMS plan, the PMS data source, the period of time over which the data was collected and the persons that performed the data analysis. All PMS records shall be stored as electronic records and organized by record type (e.g., review of monthly complaint data). Following is the PMS data in the recent years.

Year	Sales (China)/pc	Sales (Oversea)/pc	Complaints	Incidents	CAPA instigated
2020	0	0	0	0	0
2021	/	/	/	/	/

Track any complaints, incidents, adverse events, etc. that occur within the next years, and then evaluate these data to assess possible risk/benefit profiles, clinical performance and clinical safety of the device, and then update the risk management documentation and Instructions for use, etc.

6Date of the next clinical evaluation

Clinical evaluation is conducted throughout the life cycle of a medical device, as an ongoing process.

We will implement and maintain a Post Market Surveillance system that routinely monitors the clinical performance and clinical safety of the device as part of quality management system. The scope and nature of such Post Market Surveillance is appropriate to the device and its intended purpose.

The clinical evaluation is actively updated:

When we receive new information from Post Market Surveillance that has the potential to change the current evaluation;

If no such information is received, then at least updated every three years.

Post Market Surveillance system will generate new data (e.g. safety reports, results from published literature, registries and other data about device usage). These data will be evaluated by us if it has a potential to change the evaluation of the risk/benefit profile, the clinical performance and clinical safety of the device, result in changes to the risk management documents and Post Market Surveillance activities.

The updating frequency of clinical evaluation report is 5 years, to make sure the safety and effectiveness of the product in the clinical use, and the clinical evaluation report is the current and valid version.

When the updating of regulation, guidance or standard concerning on the clinical evaluation, or the updating of the product, the clinical evaluation report must be re-reviewed to make sure its current, adequate and valid.

7 Qualification of the responsible evaluators

7.1 Evaluators should possess knowledge of the following: research methodology (including clinical investigation design and biostatistics);information management (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline);regulatory requirements; and medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review and clinical data appraisal).

7.2 With respect to the particular device under evaluation, the evaluators should in addition have knowledge of: the device technology and its application; diagnosis and management of the conditions intended to be diagnosed or managed by the device, knowledge of medical alternatives, treatment standards and technology (e.g. specialist clinical expertise in the relevant medical specialty).

7.3 The evaluators should have at least the following training and experience in the relevant field: a degree from higher education in the respective field and 5 years of documented professional experience; or 10 years of documented professional experience if a degree is not a prerequisite for a given task.

7.4 Resume of editor and evaluator

Name	Cheng Xia		Gender	女
national	Chines		birthday	1987.1.15
Native place	Jiangsu Province		Education	college
professional	International business English		Contact	15380008120
E-mail	chenxia870115@163.com		Position	Office director
Training records	Date	Training items		
	2007.5	Participated in jiangsu province computer application ability assessment (intermediate - office automation), passed the assessment		
	2011.9.17	MDD 93/42/EEC, and passed the assessment		
	2011.9.22	ISO13485 internal auditor training, and passed the assessment		
	2012-7.24-7.25	GB18279-2000idtISO11135：1994 and GB/T19633-2005idt ISO11607：2003 training, and passed the assessment		
	2012.8.27	GMP training, and passed the assessment		
	2013.7.4	ISO13485 internal auditor training, and passed the assessment		
	2013.12.3-12.4	Medical device quality engineer training, and passed the assessment.		
	2013.12.18-12.21	Management representative of Medical device company training, and passed the assessment.		
	2014.11.12-11.14	《Medical device supervision and administration regulations》 training, and passed the assessment.		
	2015.7.29-7.31	Medical device register and assessment for non-implanted and passive medical device training, and passed the assessment.		
	2015.9.6-9.9	Sterile lab of medical device company training, and passed the assessment.		
	2016.4.20-4.22	ISO13485:2016 internal auditor training, and passed the assessment.		
	2016.8.24-8.26	ISO13485:2016&MDD 93/42/EEC internal auditor training, and passed the assessment.		
	2017.11.9-10	MDR training, and passed the assessment.		
	2018.4.25-27	Inspector of medical device company training, and passed the assessment.		
Work	2002.9 –	CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD		

experience	until now	
Familiar with the technology, production, quality and regulatory requirements of disposable medical devices		

8. Statement

	Chengxia	Editor/Evaluators	2020-03-26
Signature	Name	Position	Date

9.Annex

9.1 Annex1 Product full-performance test report

9.2 Annex2 Introduction of assessment person and Editor

HC-CE-KZ1-8 PMS Plan

1. We has established and <Complain control procedure> and<Vigilance system control procedure> according to annex III of MDR and ISO13485:2016. PMS will conduct according to the following procedure:

2. Collect adverse incident relating same product from the official website, evaluate these data as new input of risk management, and update risk management if necessary.

Item	Search method	Search person	Next search date	frequency
Adverse incident relating same product	http://samr.cfda.gov.cn/WS01/CL1125/	Chenxia	2020-03-21	Once a year
	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm, search product: face mask for single use.	Chenxia	2020-03-21	Once a year
	http://www.ncbi.nlm.nih.gov/pubmed/	Chenxia	2020-03-21	Once a year

According to the requirement, we searched adverse event for the similar product.

S/N	Search time/searched person	Data source	Adverse events report	New risk
1	Chenxia	CFDA (http://samr.cfda.gov.cn/WS01/CL1125/)	No	o
2	Chenxia	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm	No	o
3	Chenxia	http://www.ncbi.nlm.nih.gov/pubmed/	No	o
4	Chenxia	Customer	No	o

3. Collect complain from customer, record the following information and perform analysis from Year 2020, update the following information every year, update risk management report if the nonconformity affects product safe performance.

Year	Country	Sales QTY (Pcs)	Complain QTY (Pcs)	Rate	Complain content	If CE-marking was affixed?
2020	China	/	0	0	/	/
2020	USA	/	0	0	/	/
2020	Europe	/	0	0	/	/

4.PMCF

This product does not belong to class III, implanted or innovative products, the medium/long-term safety and clinical performance are already known from previous use, so PMCF is not required.

HC-CE-KZ1-9 Label samples

1 The label shall be designed according to requirements of 93/42/EEC, EN ISO 15223-1, EN 1041.

2 Design of label
The label shall be designed according to label control procedure.

3 Language used in label shall be in compliance with EU member states language requirements, and the accuracy of language shall be ensured.

4 Special requirements
If customer has special requirements on label, other than meeting customer’ s requirements, above-mentioned requirements shall be followed.

5 Related/supporting documents
MDD 93/42/EEC
EN ISO 15223-1: 2016
EN 1041: 2008
Label and language control procedure

(1) Primary package label(sample, just for reference)

Disposable Face Mask

REF XXXX

Specification: XXXX

Qty: XXXX

LOT XXXXXXX

Changzhou Huichun Medical Equipment Co., Ltd.
Sanhekou, Zhenglu Town, 213115 Changzhou, Jiangsu,
People's Republic of China

CE LATEX

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany
Tel: +49-40-2513175 Fax: +49-40-255726
E-mail: shholding@hotmail.com

XXXXXX XXXXXX

(2) Middle package label(sample, just for reference):

Disposable Face Mask

REF XXXX Specification: XXXX Qty: XXXX

LOT XXXXXXX

Changzhou Huichun Medical Equipment Co., Ltd.
Sanhekou, Zhenglu Town, 213115 Changzhou, Jiangsu, People's Republic of China

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Tel: +49-40-2513175 Fax: +49-40-255726
E-mail: shholding@hotmail.com

XXXXXX XXXXXX

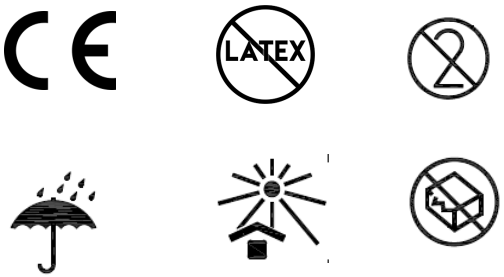
(3)Out package label(sample, just for reference):

Disposable Face Mask

REF XXXX Specification: XXXX Qty: XXXX

LOT XXXXXXX

Changzhou Huichun Medical Equipment Co., Ltd.
Sanhekou, Zhenglu Town, 213115 Changzhou, Jiangsu, People's Republic of China



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XXXXXX XXXXXX

(4) IFU(sample, just for reference)

Disposable Face Mask

REF XXXX Specification: XXXX Qty: XXXX

LOT XXXXXXX

Intended use of product
Disposable Face Mask is intended for cover the user's mouse, nose and underjaw to prevent pollutants exhaled or ejected from oral and nasal cavity under normal medical environment without the risk of body fluid and spray.
Contraindications
Persons who sensitive to related materials shall be carefully to use this product.
Not use for wound treatment environment

Use method:
(1) Peel the seal of package, take out the face mask, identify the inner side and outer side, pay attention do not contact the white side by hand.
(2) Close to face, hang the belt to two ears, place the mask clamp upon nose, pull the face mask crepe by two hands, press the clamp on nose by middle fingers of two hands, ensure the face mask cover the nose, mouse and underjaw.

Precautions
(1) This product is for single use, once open the primary package, use as soon as possible.
(2) The used product shall be treated according to medical waste requirement. Do not use if the package is damaged or expired.
(3) The used product shall be scrapped and destroyed.
(4) Pay attention to the information such as "Pay attention to check the expiry date", "Do not use if the package is damaged or expired".
(5)Read the instructions for use before use.

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