Technical Data Sheet

Medical Face Mask (Non-Sterile)

1.General Information

1.1. Legal Manufacturer
Name: Gemtier Medical（Shanghai）Inc.
Address: No. 18, Jianding Road, Fengjing Town, Jinshan District, 201502 Shanghai, China

1.2. Design and Manufacturing Site
Name: Gemtier Medical（Shanghai）Inc.
Address: No. 18, Jianding Road, Fengjing Town, Jinshan District 201502 Shanghai, China

1.3. European Authorized Representative Name:
CMC Medical Devices & Drugs, S.L.
Address: C/Horacio Lengo N° 18, CP 29006, Málaga-Spain.

1.4. Conformity Assessment Procedure
According to Regulation (EU) 2017/745 Article 52, the manufacturer follows the conformity assessment procedure relating to the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.

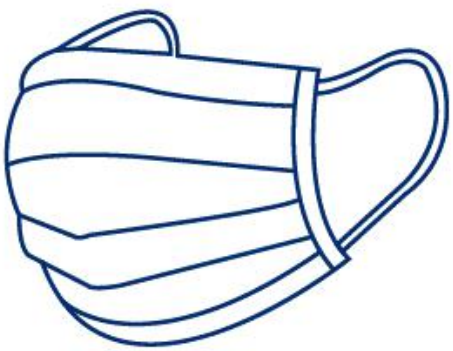
1.5. Notified Body
No involvement of a Notified Body is needed for this Non-Sterile class I device.

1.6. Declaration that no other Notified Body is used
Not applicable. No involvement of a Notified Body is needed for this Non-Sterile class I device.

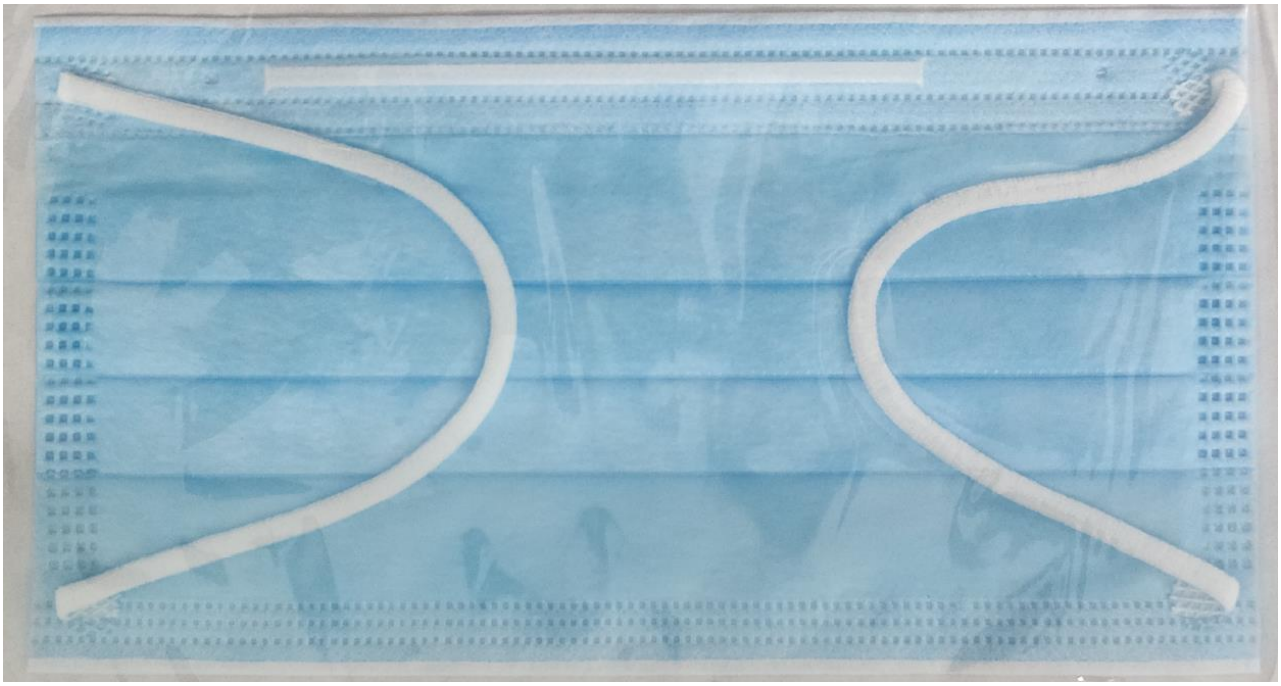
2. Product Information

2.1. Product Name and Trade Name
Name: Medical Face Masks
Type: NS2R-01, which has melt-blown material PP as filter
NS2R-02, which has PTFE as filter
This product is Type IIR mask acc. to European Standard EN 14683.

2.2. Product Schematic Diagram
Figure -Schematic Diagram of Medical Face Masks



2.3 Product Photo for Medical Face Mask



2.4. Classification

According to the definition of MDD Article 2 the medical face mask is a medical device. It is used for prevention of disease.

Medical face masks are classified as

Class: I

Rule: 1

MDR Annex VIII:

“All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.”.

Justification of the classification

Medical face mask is a non-active device for single use, and is intended to be used non-invasively. The use duration is usually less than 8 hours (short-term use).

No other rules set out in MDD Annex IX are applicable for this device.

2.5 Device Subcategory

DEVICE CODE	**Device subcategory**
MDN 1214	General non-active non-implantable devices used in health

2.6 Basic UDI-DI or Product Code

- NS2R-01

0 69 55356 11100 6

- NS2R-02

0 69 55356 11102 0

2.7. Bill of Material

We purchase all materials only from approved suppliers that have satisfied the selection and evaluation criteria as described in the SOP. The main raw materials for medical face mask are non-woven fabric and PE/PTFE.

Material for primary packaging: paper + PET/PE or PE pouch.

Table 1 Bill of Material

Part of Mask	Material
Facepiece	Non-woven fabric (PP)
Facepiece inlay	Melt-blown material (PP)
Facepiece inlay	PTFE
Ear loop	Polyester + Cotton
Nose clip	Polyethylene + steel wire
Primary Packaging material	Paper + PET/PE or PE
Outer Packaging	Box, corrugated carton

2.8 Product Performances

All tests shall be carried out on finished products or samples cut from finished products.

Bacterial filtration efficiency (BFE)

When tested in accordance with Annex B of EN 14683, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1 of EN 14683.

Breathability

When tested in accordance with Annex C of EN 14683, the differential pressure of the medical face mask shall conform to the value given in relevant type in Table 1 of EN 14683.

Splash resistance

When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1 of EN 14683.

Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical face mask ahsll be $\leq$ 30 cfu/g tested.
The number of masks that shall be tested is minimum 5 of the same batch/lot.

Biocompatibility

According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. An evaluation should be made for the medical face mask according to EN ISO 10993-1 and applicable toxicology testing regime shall be determined.

Breaking strength

The breaking strength at the connection point between each mask belt and the mask body should be not less than 10N.

Table 1 — Performance requirements for medical face masks

Test	Type I	Type II	Type IIR
Bacterial filtration efficiency(BFE),(%)	⩾95	⩾98	⩾98
Differential pressure (Pa/cm^2)	<40	<40	<60
Splash resistance pressure (kPa)	Not required	Not required	⩾16,0
Microbial cleanliness (cfu/g)	⩽30	⩽30	⩽30

2.9 Shelf-Life or Lifetime

The shelf-life is 2 years after Production.

The uninterrupted use duration of the device is usually less than 8 hours.

3. Labelling

For Medical face masks, information supplied by the manufacturer comprises the details on the label.

As labelling on the device itself is not practicable, the information needed to use the device safely is set out on the primary packaging and on the sales packaging (carton).

Labelling includes all applicable information required by MDR, Annex I, Chapter III, section 23.2 and EN 1041 “Information supplied by the manufacturer of medical devices”.

This information takes the form of internationally recognized symbols. The symbols used are conform to the harmonized standard EN ISO 15223-1.

Package labeling includes product identification, lot number, product description, used by date, manufacturing date, do not re-use, do not use if package is damaged, caution, consult instruction for use, manufacturer and EU representative information, etc.

The Organization ensures that only approved packaging labels will be used and distributed together with the products.

Each product unit is properly packaging to ensure its packing integrity without any damages or deterioration in nature. The production lot number and manufacturing date are identified.

The packaging and storage activities are described in the SOP Preservation of Products.

All packaging materials are properly labeled according the SOP Identification and Traceability.

4. Instructions for Use

Instructions for Use (IFU) are provided with the medical devices together by the organization to inform the device user or medical staff of the product’s proper use and of any precautions to be taken.

The instructions for use are provided in accordance with MDR, Annex I, Chapter III, section 23.4, include, where appropriate, detailed informing for the users and/or patients and allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken.

The meaning of symbols used on the label is explained in the IFU.

The “Instructions for Use” include but not limited to the contents below:

i. Product name;

ii. Description/indications;

iii. Specification;

iv. Warnings and Precautions;

v. Instruction for use;

vi. Storage conditions;

vii. Shelf life;
viii. Product disposal;
ix. Explanation of symbols used on labels and IFU;
x. Manufacturer and EC REP information;
xi. Version and issued date.
xii. CE (with notify body number if required).

The target markets within EU are Ireland, England, Scotland and Wales with English as an official language. Other markets and the required languages (IFU, labelling) within EU markets will follow after other target markets confirmed.
If other languages are required by local distributors or users, we will engage a translation of the instructions for use by a qualified translation office. The translated text will be sent to the local distributor for checking the correctness of the translation.

5.Packaging :
Medical face masks are primarily packed in the paper + PET/PE pouch or PE pouch.

For packaging with paper + PET/PE pouch:
Each pouch contains 10 masks.
5 pouches are packed into a sales box.
Each shipping container contains 2000 medical face masks.
Each carton size is 55.5*44.5*42cm, Gross weight: 11KG/carton

For packaging with PE pouch:
Each pouch contains 20 masks.
5 pouches are packed into a sales box (100 masks).
Each shipping container contains 4000 medical face masks.
The packaging process is specified in work instruction.

The sealing process has been validated, refer to validation report JT-SVF-06-035-2019.

6. Product Verification and Validation

6.1. Pre-Clinical Evaluation
Pre-clinical evaluation was performed in framework of design validation. It includes functional and performance testing acc. to the product specification.
The documentation contains the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of the MDR and in particular the applicable general safety and performance requirements.
The tests confirm the pre-clinical safety of the device and its conformity with the specifications.
The test results refer to section 8.2.
Other tests, e.g. Biocompatibility have also been performed, s. section 8.3.

6.2. Product Testing (Performance and Safety)
Medical face masks are designed, manufactured and tested acc. to the standard series EN 14683:2019+AC:2019.
Performance, safety and functional testing has been performed in product type examination.
The performance and safety test includes bacterial filtration efficiency (BFE), breathability, splash resistance, microbial cleanliness (Bioburden), breaking strength.

The test was conducted by the accredited laboratory TÜV SÜD Products Testing (Shanghai) Co., Ltd. with representative samples of medical face masks.
In addition, batch-release test is performed for each production batch including safety and performance test and bioburden test. The product specification and acceptance criteria are described in section 27 “Product performances ” of the Technical Documentation.

6.3. Biocompatibility Evaluation

Materials in direct or indirect contact with the patient or user are identified and specified in bill of material. All these materials are bridely used in medical devices and have been proved as biocompatible and safe materials.
Biocompatibility Evaluation is based on laboratory tests as defined for the product category in table A.1 of EN ISO 10993-1.
For the medical face masks following consideration can be taken:
Nature of body contact: Intact skin or indirect contact with mucosal membrane;
Contact duration: A — limited (≤ 24 h).
According to ISO 10993-1:2018 following tests should be done:
- Cytotoxicity acc. to EN ISO 10993-5;
- Sensitization acc. to EN ISO 10993-10;
- Irritation or intracutaneous reactivity acc. to EN ISO 10993-10.

All required tests were conducted with representative samples of Medical face masks with satisfied results.

Cytotoxicity

In Vitro Cytotoxicity Test Report
The MTT method results showed that the cytotoxicity ration of the 100% test article extract met the requirements. The test article extract did not show potential toxicity to L-929 cells.
Sensitization

Skin Sensitization Test Report

The positive rate of all test groups was 0%. All animals were not found abnormal clinical symptoms except skin reactions. All animals were normal weight changed. The sample extract chowed no signification evidence of causing skin sensitization in the guinea pig.
Irritation or intracutaneous reactivity

Skin Irritation Test Report

The response of skin on testing sites was not more severe than that on the control sites. The primary irritation index for the test article was calculated to be 0. No abnormal clinical symptoms except skin reactions was found for all animals. The test result showed that the test article extract did not induce skin irritation in rabbit.
In addition, the non-woven material and primary packaging material have also been tested for biocompatibility.
Similar masks have been manufactured and sold since decades. There were no incidents or serious complaints in relation to biocompatibility. This fact supports the evidence for good biocompatibility with the products.
Evaluation of biocompatibility is a continuous process. For this purpose, post-production experience will be gathered and analysed. As soon as there are abnormalities in use of the medical face masks, a new evaluation will be started.

7. **EU Declaration of Conformity**

As the device in question meets the General Safety and Performance Requirements set out in Annex I of MDR which apply to them, a Declaration of Conformity is issued by manufacturer, refers to Appendix 11.1: Declaration of Conformity.
After completion of the batch-release tests with satisfied results, the production batch will be released with a batch-related final inspection report. This final inspection report is considered as a part of declaration of conformity

for the produced batch.
The EU declaration of conformity shall contain all of the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The Basic UDI-DI as referred to in Part C of MDR Annex VI;
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;
5. Risk class of the device in accordance with the rules set out in Annex VIII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;
7. References to any CS used and in relation to which conformity is declared;
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
9. Where applicable, additional information;
10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.