World Health Organization

Technical specifications for pre-market assessment of medical masks

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ISBN 978-92-4-007895-6 (electronic version)
ISBN 978-92-4-007896-3 (print version)

Suggested citation. Technical specifications for pre-market assessment of medical masks. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Design and layout: Genève Design

Contents

Acknowledgements

The development of this document was coordinated by Adriana Velazquez Berumen, Team lead, Medical Devices and In Vitro Diagnostics, Health Products and Standards, WHO, Geneva, Switzerland.

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Nicolo Binello (WHO Technical Officer) and Daniela Rodriguez Rodriguez (WHO consultant) selected the members of the Technical Advisory Group and ensured technical expertise and gender and regional distribution.

This document was developed with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Acronyms and abbreviations

ASTM	American Society for Testing and Materials
COVID-19	coronavirus disease
EN	European standard
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
PAHO	Pan American Health Organization
PPE	personal protective equipment
PQ	prequalification
QMS	quality management system
ToC	table of contents
UMDNS	Universal Medical Device Nomenclature System
WHO	World Health Organization

1. Introduction

The purpose of this document is to provide technical specifications to medical mask manufacturers. The document is intended mainly for manufacturers but could also be used as a reference by regulators.

The manufacturer should consider the technical specifications outlined as minimum requirements in order to ensure that the medical mask has been designed, evaluated and validated in conformity with those requirements and is therefore safe and effective. The manufacturer shall provide evidence of the safety and performance of the medical mask to demonstrate that it performs as intended and as declared in the indications for use.

Any medical mask that has undergone assessment by a stringent regulatory authority may proceed to an abridged process, whereas other medical masks require a full assessment of the documentation to ensure compliance with the technical specifications. The regulator may also inspect manufacturing sites to ensure that they meet the technical requirements and that there is a fully implemented quality management system (QMS), a risk management system, product stability, routine manufacture and sufficient capacity to ensure reliable delivery. Independent evaluation of the technical and performance characteristics of the medical mask might be conducted to ensure that it meets the technical specifications.

The final outcome of the assessment depends on:

- the results of the dossier review to determine whether it meets the technical specifications and acceptance of the corrective action plan, if required;
- the results of the site inspection(s) and acceptance of the corrective action plan, if required; and
- meeting the minimum acceptance criteria in the laboratory evaluation.

When a decision to approve a mask has been made, a market authorization is issued by a regulatory authority.

The manufacturer is obliged to conduct post-market activities to continue to ensure the quality, safety and performance of the medical mask. The manufacturer is also obliged to notify the regulatory agency of any changes to the product or the QMS, so that these may be evaluated to determine any implications in the list of products that have received market authorization.

2. Methods

The document was prepared in collaboration with members of a Technical Advisory Group that was established to review and comment on the technical specifications for medical masks. The members of the group were selected from a list of experts who had contributed to WHO technical documents related to personal protective equipment (PPE) established as part of the response to coronavirus disease (COVID-19). In addition, WHO requested regional focal points to nominate experts in PPE, and a call was opened among biomedical engineering networks. After an initial selection of experts, the list was reviewed to ensure balanced representation of engineers, clinicians and regulators, gender distribution and representation of all six WHO regions. The selected experts were then formally invited to participate in the Technical Advisory Group. Those who were unable to attend were replaced by alternative experts on PPE. All the experts completed a form for declaration of interests. No conflicts of interest were found.

Altogether, four Technical Advisory Group meetings were held, two on 11 and 22 August, before a public consultation to review the technical specification, and two on 10 and 21 November, 2022, after the public consultation to deliberate on the comments received.

The draft document was posted on the WHO website for public consultation between 1 September and 10 October 2022. Various stakeholders, including industry and professional associations, were informed of the consultation in order to provide feedback. Comments were received for consideration from Nagwa Hasanin

(United Nations Children's Fund), Selcen Kilinc-Balci (US Center for Disease Control and Prevention) and Madison Moon (WHO).

The document is based on a review of the WHO technical series on medical devices, the technical specifications for personal protective equipment for COVID-19, medical masks available on the market, medical masks approved by stringent regulatory agencies and analysis of international and regional standards on medical masks (see References). It includes a discussion and comparison of adequately tested medical masks and standards to build consensus for the global market.

In this document, the following verbal forms are used:

- "shall" indicates that the manufacturer is required to comply with the technical specifications;
- "should" indicates that it is recommended that the manufacturer comply with the technical specifications but are not required to do so; and
- "may" indicates that the technical specifications are suggested for testing but are not requirements.

The document will be updated regularly as new information becomes available.

3. Application of these specifications

The medical mask manufacturer shall comply with the specifications stated in this document and provide evidence that the medical mask is safe, effective and performs as intended by the manufacturer and therefore conforms to the essential principles of safety and performance. The manufacturer shall comply with the requirements for establishment as manufacturer, medical device technical specifications and quality management procedures and submit documentation as evidence as prescribed in Table 1 of the table of contents for market authorization of non-in-vitro diagnostic medical devices by the International Medical Device Regulators Forum (see Annex).

4. Other guidance documents

This document should be read in conjunction with other relevant WHO guidance, including:

WHO PQ:

- Technical Guidance Series 1 for WHO Prequalification – Diagnostic assessment *(1)*
- WHO prequalification *(2)*

WHO guidance:

- Infection prevention and control *(3)*
- Preventing infections in health workers *(4)*
- Medical devices *(5)*
- Technical specifications of personal protective equipment for COVID-19, 2020 *(6)*
- COVID-19 infection prevention and control. Living guideline: mask use in community settings *(7)*
- WHO recommendations on mask use by health workers, in light of the Omicron variant of concern: WHO interim guidelines, 22 December 2021 *(8)*
- Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages *(9)*
- COVID-19 infection prevention and control living guideline: mask use in community settings, 22 December 2021 *(10)*

Other documents:

- International Medical Device Regulators Forum. Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents *(11)*
- European Standards. UNE EN 14683:2019+AC:2019: Medical face masks. Requirements and test methods. 2019 *(12)*
- American Society for Testing and Materials (ASTM) International. F23 Committee. Specification for performance of materials Used in medical face masks *(13)*

5. Technical specifications for medical masks

5.1 Intended use

A medical mask intended for market authorization shall be accompanied by a sufficiently detailed statement of intended use, which shall also indicate the type of medical mask. The intended use of medical masks is as follow:

- by health-care workers as a barrier to help protect them from liquid splashes and sprays, such as blood, to which they might be exposed during certain medical procedures; and
- to capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria.

5.2 Intended environment or setting for use

In the absence of aerosol-generating procedures, WHO recommends that health workers who provide care to patients with suspected or confirmed COVID-19 should wear a medical mask.

5.3 Scope

This document provides the following technical specifications for medical masks:

- only for medical masks types I and IIR or equivalent;
- not for medical masks that contain drugs, biologicals, nanoparticles or antimicrobial or antiviral agents; and
- not for reusable masks, respirators or textile masks.

5.4 Diversity of product types and users

Medical masks are defined as surgical or procedure masks that are flat or pleated and affixed to the head with straps around the ears, head or both. Their performance characteristics are tested by standardized test methods (ASTM F2100, EN 14683 or equivalent) and should balance high filtration, adequate breathability and, optionally, resistance to fluid penetration.

A medical mask is fluid-resistant, is intended to be placed over the nose and mouth of medical personnel, patients or the public who are infected or displaying symptoms to create a physical barrier from the mouth and nose of the wearer. Its objective is to prevent transmission of fluid, spray and/or droplets during surgery or patient examination. Medical masks are graded as type I or IIR according to the degree of protection provided, including fluid resistance.

A medical face mask, or surgical mask, is an item of protective clothing designed to protect portions of the wearer's face, including the mucous membranes of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures (3.1.7 ASTM F3502-21).

A minimum requirement for type-I medical face masks is that they should be used only by patients and the general public for source control in order to reduce the risk of spread of infections, particularly in epidemic or pandemic situations. Type I medical masks are not intended for use by health-care workers in operating rooms or other medical settings with similar requirements (EN 14683;2019) *(12)*.

Type II masks are intended principally for use by health-care professionals in operating rooms or other medical settings with similar requirements *(12)*.

Type IIR masks are intended principally for use by health-care workers to protect them from splashes of potentially contaminated liquids *(12)*.

5.5 Applicability of supporting evidence for the medical mask under review

5.5.1 The manufacturer shall submit supporting documents and reports of performance of the QMS as evidence for assessment.

5.5.2 Training

5.5.2.1 The manufacturer shall provide training material or instruction for use to end-users of the medical mask.

5.5.2.2 The manufacturer shall provide a simple video or step-by-step instructions on use of the medical mask. Example: https://youtube/ciUniZGD4tY

5.5.3 Warranty

The manufacturer shall provide information on warranty to the end-user of the medical mask.

6. Table of requirements for medical masks

The table of requirements is based on the International Medical Device Regulators Forum (IMDRF) Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents (ToC) *(11)* format to assist the manufacturer to submit documentation and evidence similar to market authorization documentation or product registration submission. IMDRF/RPS WG/N13 FINAL:2019 (Edition 3)*(11)* is attached to this document as the Annex. The classification matrix defines whether a heading is required, not required, optional or conditionally required for a given submissions type. As the IMDRF ToC is comprehensive, not all subheadings are required for each submission by a regulatory agency. As a result, the numbering in Table 1 is not always continuous. This was done to maintain consistency between the sections required in a product dossier for assessment and the numbering in the IMDRF ToC format. The table of contents for medical masks is shown in Table 1.

The information submitted in the IMDRF nIVD ToC should be supported by relevant documents, such as copies of labels, certificates and reports. When such documents are cited in the IMDRF nIVD ToC, each must be submitted in full, with all pages. The documents must be legible and within the stated period of validity. All certificates and reports submitted must be signed and dated by the person who is authorized to issue the report.

Table 1. Table of contents for medical masks

1 Regional administrative		Description
1.01	Covering letter	The manufacturer shall indicate the type of submission being made.
1.02	Submission table of contents	
1.03	List of terms and acronyms	
1.04	Application form and administrative information	The name, full address, primary contact of the applicant and manufacturer
1.05	List of device(s)	The manufacturer shall provide a complete list of the configurations of the medical devices subject to the submission, including any accessories.
1.06	Quality management system, full quality system or other regulatory certificates q q q	The manufacturer shall use a QMS based on ISO13485:2016 or equivalent certification, accredited by a signatory of the International Accreditation Forum Multilateral Recognition Arrangement. The validity of the certificate shall be specified.
1.07	Free sale certificate of certificate of marketing authorization	• A list of free sale certificates obtained by various countries shall be provided. The list of countries in which the medical device is marketed shall include: • copies of approval letter(s) from each reference agency and, • for devices marked Conformité européenne, the European Union declaration of conformity by the product owner must be submitted, in addition to the European Commission certificate issued by the notified bodies.
1.08	Expedited review documentation	The report shall indicate whether expedited review has been granted by a regulatory authority. The evidence certificate and or documentation shall be submitted.
1.09	User fees	
1.10	Pre-submission correspondence and previous interactions with regulators	The manufacturer shall provide details of pre-submission correspondence, previous interactions with regulators and the status of the submission.
1.11	Acceptance for review checklist	The manufacturer shall provide the checklist of acceptance for review provided in the marketing submission.
1.12	Statements, certificates, declarations of conformity	Declaration by the manufacturer of compliance to the technical specifications
1.12.01	Performance and voluntary standards	The manufacturer shall list the relevant performance and voluntary standards of the product.
1.12.04	Statement of indications for use with prescription and/or over-the-counter designation	
1.12.05	Statement of truthfulness and accuracy	The manufacturer shall attest to the truthfulness and accuracy of the statement in the submission.

1.12.07	Declaration of conformity	The manufacturer shall provide statements, certificates or declarations of conformity to the technical specification and the requirements stated in this document.
2 Submission context		
2.01	Chapter table of contents	
2.02	General summary of the submission	The manufacturer shall provide the name and address of the manufacturing site. All manufacturing site(s) is (are) a fully owned subsidiary(ies) or contractor(s) of the legal manufacturer. The name of the responsible person and contact person shall be provided.
2.03	Summary and certifications for premarket submissions	
2.04	Device description	The manufacturer shall provide details of the medical mask, such as a summary description, the principles of operation, technology, functionalities and features of packaging. It shall include labelled pictorial representation (diagrams, photographs, drawings), if applicable. It should also include the history of development, references and comparisons to similar and/or previous versions of the medical mask. The intended use of a medical mask shall be stated as follows: • by health-care and community workers as a barrier to protect them from liquid splashes and sprays, such as blood, during certain medical procedures; and • to capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria.
	General design requirements	The medical mask shall be designed to fit closely over the nose, mouth and chin of the wearer and fit closely at the sides, according to EN 14683:2019 or equivalent standards. The general design details shall include the following: i) Fittings ii) Sizes: Adult/child iii) Types: a. Ear loops b. Head loops c. Tie-on d. Moulded iv) Mask style: a. duck bill b. flat pleated c. cone shaped d. pouch v) Nose clamp vi) Strap strength

2.04.01	Comprehensive description and principle of operation of the device	A medical mask shall protect both the patient and the health-care worker from the transfer of microorganisms, body fluids and particulate material. A detailed description of the attributes of the medical mask is necessary to explain how it functions, the scientific basis of the device, the components, materials and accessories used in its operation and of its packaging. A complete description of each functional component, material or ingredient of the mask should be provided, with labelled pictorial representation of the device in the form of diagrams, photographs or drawings, as appropriate.
2.04.02	Description of device packaging	
2.04.03	Design before and after COVID-19	The manufacturer may provide any details of innovative design.
2.04.04	History of development	
2.04.05	Reference and comparison with similar and/or previous versions of the device	
2.04.06	Discussion of substantial equivalence	
2.05	Indications for use and/ or intended use and contraindications	
2.05.01	Intended use, intended purpose, intended users, indications for use	The intended use of the medical mask is: • by health-care and community workers as a barrier to protect them from liquid splashes and sprays, such as blood, during certain medical procedures; • to capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria Indications for use, with a general description of the disease or condition that the mask will prevent, cure or mitigate; includes a description of the patient population for which the mask is intended.
2.05.02	Intended environment or setting for use	All areas, to prevent infection. In the absence of aerosol-generating procedures, WHO recommends that health workers who are providing care to patients with suspected or confirmed COVID-19 should wear a medical mask. Used as part of precautions against droplet transmission in any circumstance (18)
2.05.02.01	Context-dependent requirements	Environmental temperature
2.05.02.02	Normal working conditions	• Temperature: 5–40 °C • Relative humidity: 15–90%

2.05.02.03	Storage conditions	• Temperature: – 20 °C to + 60 °C • Relative humidity: ≤ 93%
2.05.03	Paediatric use	
2.05.04	Contraindications for use	The manufacturer shall list the contraindications, with a general description of the diseases or conditions and the patient populations for which the mask should not be used.
2.05.06	Availability of the product	The manufacturer shall issue a declaration that the maskwill not be discontinued within the next 5 years.
2.06	Marketing authorization	Includes a list of regulatory approvals or marketing clearances obtained, including the registration status of any pending request for market clearance: • list of countries in which the medical mask is marketed. • copy(ies) of approval letter(s) from each reference agency • for devices marked Conformité européenne, the European Union declaration of conformity by the product owner must be submitted, in addition to the European Commission certificate issued by the notified bodies.
2.06.01	Global marketing history	The global marketing history of the mask, including where it is currently authorized to be marketed and the experience in those region(s) (e.g., any incidents and/or recalls) • List of countries in which the medical maskis marketed • Date (accurate to MM/YYYY) and country in which the maskwas first introduced for commercial global distribution • Registration status (i.e. submitted, not submitted, pending approval, rejected or withdrawn) and approved intended use and indications of the medical mask in reference agencies, in tabular format. If the mask has been withdrawn or rejected by any reference agency, the reason for rejection or withdrawal is to be provided. • Important safety and performance information, including a summary of reportable incident and recalls • Global incident reports and recalls • Latest inspection reports

2.06.02	Global incident reports and recalls	• The manufacturer shall include a summary of reportable incidents and recalls for the medical mask since its first introduction onto the global market, in tabular format • The manufacturer shall ensure that all incidents due to mask failure and personal injury are investigated and reported to the health-care delivery organization. The establishment shall carry out corrective and preventive actions to eliminate or reduce the risk of recurrence of such incidents. • If there have been no incidents, the manufacturer shall provide an attestation on company letterhead that there have been no adverse events since commercial introduction of the mask globally. • The report shall comply with the medical device regulation and policies of the importing country. • This section should include ongoing incident reports and status. The manufacturer shall establish an effective procedure for recall, describing actions to be taken in initiating and implementing timely recall to meet the requirements of the medical device regulation and policies of the importing country. The manufacturer shall notify the health-care delivery organization and regulatory authority, advise users and facilitate removal of the mask from service, if required. A summary shall be provided of recalls of the medical mask since its first introduction onto the global market, including ongoing recalls and their status.
2.06.03	Sales, incident and recall rates	
2.06.04	Evaluation and inspection reports	The manufacturer shall report planned changes in product design specifications, manufacturing location and manufacturing methods or ingredients. The manufacturer shall submit the latest evaluation and inspection reports

3 Non-clinical evidence

3.01	Chapter table of contents
3.04	Standards

3.04.01	List of standards	In designing and manufacturing the medical mask, the manufacturer shall comply with the following standards: • ISO13485:2016 • ISO14971:2019 • ASTM F2100/EN 14683 or equivalent • EN 14683:2019; Annex B and C or • ASTM F2100-20 and 21 or equivalent standard • ASTM F2101/EN 14683:2019 or equivalent • ASTM F1862 /EN 14683:2019 or equivalent • ISO 2859-1:1999 • ISO17025:2017 • ISO11737-1:2018 or equivalent • ASTM D3776 • ISO 811:2018 or equivalent standard • ISO10993 -1, ISO10993 -5, ISO10993 -10, ISO10993 -23 • IEC 62366-1:2015 / EN 62366 • ISO 15223-1:2016 and EN ISO 20417:2021 or equivalent
3.04.02	Declaration and/or certification of conformity	
3.05	Non-clinical studies	Design verification and validation documents. including • preclinical studies • metrological requirements The manufacturer shall comply with requirements and test methods for medical masks based on ASTM F2100/EN 14683 or equivalent. Detailed parameters of medical mask requirements, as follows; filtration: bacterial filtration efficiency breathability: differential pressure (Pa/cm2) fluid resistance: penetration by synthetic blood (kPa)
3.05.01	Study description, study identifier, date of initiation shall be provided for medical mask testing.	Testing to be conducted by an ISO 17025-accredited laboratory. Test methods based on European standard (EN) 14683:2019 or equivalent The manufacturer shall submit the study design based on EN 14683:2019 or equivalent and the related full report.
3.05.02	Sampling procedures for inspection shall be based on ISO 2859-1:1999	

3.05.03	Physical performance, characteristics, clinical evaluation	The manufacture shall attach evidence supporting the performance, physical or mechanical properties of the medical mask The requirements for both type I and type IIR medical masks shall be based on the following standards: EN 14683:2019 or equivalent standards: Types: I and IIR based on Table A and Table B. Medical face masks – Requirements and test methods EN 14683:2019 Annex B and C or ASTM F2100-20 and 21 or equivalent standard
3.05.03.01	Performance requirements The standard test method for evaluating the bacterial filtration efficiency of medical masks shall be based on ASTM F2101/EN 14683:2019 or equivalent The manufacturer shall submit the study design based on EN 14683:2019 or equivalent standard.	Type I performance The bacterial filtration efficiency of a type I medical mask shall conform to the minimum value: Bacterial filtration efficiency (3.0 µm particle size) (%): range ≥ 95%
		Type IIR performance The bacterial filtration efficiency of a type IIR medical mask shall conform to the minimum value: Bacterial filtration efficiency (3.0 µm particle size) (%): range ≥ 98%
3.05.03.02	Microbial cleanliness Studies of microbial cleanliness (colony-forming units/g) shall be based on EN 14683:2019. The number of masks to be tested is a minimum five from the same batch or lot. The testing procedure shall be as described in Annex D of EN 14683:2019 or equivalent standard.	When tested according to EN ISO 11737-1:2018, the bioburden of the medical mask shall be ≤ 30 colony-forming units/g The evidence for microbial cleanliness and bioburden (colony-forming units/g) for both type I and type IIR medical masks shall be provided.
3.05.04	Physical and mechanical characterization The manufacturer shall submit evidence of the differential pressure and synthetic blood penetration (splash resistance pressure) tests conducted on the medical mask	
3.05.04.01	Comfort characteristics of the medical mask	US military standard 36945C 4.4.1.1.1 method 1 or EN 14683:2019 or equivalent standard
3.05.04.02	Basis weight	ASTM D3776
3.05.04.03	Dimensions	The manufacturer shall provide details of the physical characteristics of the medical mask: • size • dimensions • tensile strength • other specifications relevant to user needs, e.g. impact resistance

3.05.04.04	Breathability and differential pressure To evaluate differential pressure (Pa/cm2), the method based on US military standard 36945C 4.4.1.1.1 Method 1 or EN 14683:2019 or equivalent standard	**Type I performance** Differential pressure (Pa/cm2) shall be < 40 Pa/cm2 **Type IIR performance** Differential pressure (Pa/cm2) shall be < 60 Pa/cm2
3.05.04.05	Method for testing resistance to penetration by synthetic blood (splash resistance pressure) (mm Hg or kPa) based on ASTM F1862 /EN 14683:2019 or equivalent	**Type IIR performance** Synthetic blood penetration (splash resistance pressure) shall be > 120 mm Hg or > 16 kPa
3.05.05	Chemical and material characterization	List of materials and complete chemical, biological and physical characterization of the materials of the medical mask in contact either directly or indirectly with a human body
3.05.05.01	Materials used in the medical mask	Evidence that the materials used in the medical mask comply with ASTM F2100:2019 or equivalent and/ or ISO 22609:2004 Clothing for protection against infectious agents – Medical face masks
3.05.05.02	Materials used in the medical mask, textile resistance to water penetration	ISO 811:2018 Textiles – Determination of resistance to water penetration – hydrostatic pressure test
3.05.05.03	Study description, study identifier, date of initiation	
3.05.06	Biocompatibility and toxicological evaluation	The report should include an assessment of the evidence for biocompatibility and of toxicology based on ISO 10993. **Type IIR performance** Biocompatibility The medical mask shall pass evaluation by: • ISO 10993-1:2018 Biological evaluation of medical devices and testing within risk management • ISO 10993-5:2021 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization • ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation
3.05.06.01	Study description, study identifier, date of initiation	
3.05.07	Non-material-mediated pyrogenicity	The report should include an assessment of the evidence for pyrogenicity, such as endotoxin levels
3.05.07.01	Study description, study identifier, date of initiation	

3.05.08	Safety of materials of biological origin (human/animal) The report should include an assessment of the evaluations performed to demonstrate the safety of materials of biological origin.	Optional
3.05.08.01	Certificates	Optional
3.05.08.02	Study description, study identifier, date of initiation	Optional
3.05.08.02.01	Summary	Optional
3.05.08.02.02	Full report	Optional
3.05.08.02.03	Statistical data	Optional
3.05.11	Usability and human factors	The report shall include an assessment of studies of the instructions for use and/or mask design relevant to the intended user in terms of impact of human behaviour, ability, limitations and other characteristics of the mask to ensure that it can perform as intended, based on: IEC 62366-1:2015 / EN 62366 Medical devices standard Part 1: Application of usability engineering to medical devices. IEC 60601-6 (added recently) Parts 1–6: General requirements for basic safety and essential performance – Collateral standard: usability
3.05.11.01	Study description, study identifier, date of initiation	
3.06	Non-clinical bibliography	The report shall include a summary of the sources in the non-clinical bibliography, including a review to support the safety and effectiveness of the medical mask
3.07	Expiration period and package validation	
3.07.02.02	Shelf life	The minimum shelf life for a single-use medical mask must be 5 years.
3.07.02.03	Environmental requirements	
	Context-dependent requirements	Handling environmental temperature
	Normal working conditions	Temperature: 5–40 °C Relative humidity: 15–90%
	Storage conditions	Temperature: – 20 °C to + 60 °C Relative humidity ≤ 93%
	Transport and storage (if relevant)	Storage environment humidity: 10–95% relative humidity
	Information on particular storage conditions (temperature, pressure, light, humidity)	Storage environment temperature: – 20 to + 60 °C

5 Labelling and promotional material		
5.01	Chapter table of contents	
5.02	Product and package labels	These will include a description of the materials of the product or package labels provided by the manufacturer, primary and secondary labels in their original colour and the accessories, as applicable, shall be provided. The proposed labelling should be sufficient to describe the medical mask, its intended use and directions for its use (at least in English). Compliance of the symbols used on the labels and the information supplied with ISO 15223-1:2016 and EN ISO 20417:2021 or equivalent should be considered.
	Information on the label	Samples of labels on the mask and its packaging are to be provided. The proposed labelling should be sufficient to describe the mask, its intended use and instructions for its use (at least in English). • name and/or trademark of the manufacturer • model or product reference • information on particular storage conditions (temperature, pressure, light, humidity) • shelf life • lot and batch number • model number • manufacturer's name and contact ISO 15223-1:2016 and EN ISO 20417:2021 or equivalent should be considered. https://www.iso.org/standard/69081.html
	Symbols	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	Any identification or coding	Unique medical mask identification Naming code and term as per any of the following: Global Medical Device Nomenclature (GMDN), Universal Medical Devices Nomenclature System (UMDNS), United Nations Standard Products and Services Code (UNSPSC) or European Medical Device Nomenclature (EMDN)

5.03	Package insert and instructions for use	The manufacturer shall include the procedures and methods for safe use of the medical mask. Instructions necessary for safe use of the mask shall, to the extent possible, be included on the mask itself and/or on its packaging in other formats. This should include information on indications, contraindications, warnings, precautions, potential adverse effects and conditions during normal use to maintain the safety and effectiveness of the mask
	Warnings	The manufacturer shall provide information on specific hazard alerts before use of the mask.
	Precautions	The manufacturer shall indicate the precautions and special care necessary for safe, effective use of the mask.
5.04	e-Labelling	
5.07	Technical and operators manuals	
5.09	Product brochures	
5.10	Other labelling and promotional material	
6A Quality management procedures		
6A.01	Covering letter	
6A.02	Chapter table of contents	
6A.03	Administrative	
6A.03.1	Product descriptive information	
6A.03.2	General manufacturing information	
6A.03.3	Required forms	
6A.04	Quality management system procedures	
6A.05	Management responsibilities procedures	
6A.06	Resource management procedures	
6A.07	Product realization procedures	
6A.08	Design and development procedures	
6A.09	Purchasing procedures	
6A.10	Production and service controls procedures	
6A.11	Control of monitoring and measuring devices procedures	
6A.12	QMS measurement, analysis and improvement procedures	
6A.13	Other QMS procedures information	

6B Quality management system device-specific information	
6B.01	Chapter table of contents
6B.02	Quality management system information
6B.03	Management responsibilities information
6B.04	Resource management information
6B.05	Device-specific quality plan
6B.06	Product realization information
6B.07	Design and development information
6B.08	Purchasing information
6B.09	Production and service controls information
6B.10	Control of monitoring and measuring devices information
6B.11	QMS measurement, analysis and improvement information
6B.12	Other device-specific QMS information

References

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Annex. Matrix for classification in the International Medical Device Regulators Forum Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents

IMDRF TOC CHAPTER 1 – REGIONAL ADMINISTRATIVE		
1.01	Cover Letter	R
1.02	Submission Table of Contents	R
1.03	List of Terms/Acronyms	R
1.04	Application Form/Administrative Information	
1.05	Listing of Device(s)	R
1.06	Quality Management System, Full Quality System or Other Regulatory Certificates	R
1.07	Free Sale Certificate/ Certificate of Marketing authorization	R
1.08	Expedited Review Documentation	R
1.09	User Fees	
1.10	Pre-Submission Correspondence and Previous Regulator Interactions	R
1.11	Acceptance for Review Checklist	R
1.12	Statements/Certifications/Declarations of Conformity	R
1.12.01	Performance and Voluntary Standard	R
1.12.02	Environmental Assessment	NR
1.12.03	Clinical Trial Certifications	NR
1.12.04	Indications for Use Statement with Rx and/or OTC designation Enclosure	R
1.12.05	Truthful and Accurate Statement	R
1.12.06	USFDA Class III Summary and Certification	NR
1.12.07	Declaration of Conformity	R
1.13	Letters of Reference for Master Files	R
1.14	Letter of Authorization	NR
1.15	Other Regional Administrative Information	NR
CHAPTER 2 – SUBMISSION CONTEXT		
2.01	Chapter Table of Contents	R
2.02	General Summary of Submission	R
2.03	Summary and Certifications for Premarket Submissions	R
2.04	Device Description	R
2.04.01	Comprehensive Device Description and Principle of Operation	R
2.04.02	Description of Device Packaging	R
2.04.03	History of Development	R
2.04.04	Reference and Comparison to Similar and/or Previous Generations of the Device	R
2.04.05	Substantial Equivalence Discussion	R

2.05	Indications for Use and/or Intended Use and Contraindications	R
2.05.01	Intended Use; Intended Purpose; Intended User; Indications for Use	R
2.05.02	Intended Environment/Setting for use	R
2.05.03	Pediatric Use	R
2.05.04	Contraindications For Use	R
2.06	Global Market History	R
2.06.01	Global Market History	R
2.06.02	Global Incident Reports and Recalls	R
2.06.03	Sales, Incident and Recall Rates	R
2.06.04	Evaluation/Inspection Reports	R
2.07	Other Submission Context Information	NR
CHAPTER 3 – NON-CLINICAL EVIDENCE		
3.01	Chapter Table of Contents	R
3.02	Risk Management	NR
3.03	Essential Principles (EP) Checklist	NR
3.04	Standards	R
3.04.01	List of Standards	R
3.04.02	Declaration and/or Certification of Conformity	NR
3.05	Non-clinical Studies	R
3.05.01	Physical and Mechanical Characterization	R
3.05.01.01	[Study description, study identifier, date of initiation]	
3.05.01.01.01	Summary	R
3.05.01.01.02	Full Report	R
3.05.01.01.03	Statistical Data	R
3.05.02	Chemical/Material Characterization	R
3.05.02.01	[Study description, study identifier, date of initiation]	R
3.05.02.01.01	Summary	R
3.05.02.01.02	Full Report	R
3.05.02.01.03	Statistical Data	R
3.05.03	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	NR
3.05.03.01	[Study description, study identifier, date of initiation]	NR
3.05.03.01.01	Summary	NR
3.05.03.01.02	Full Report	NR
3.05.03.01.03	Statistical Data	NR
3.05.04	Radiation Safety	NR
3.05.04.01	[Study description, study identifier, date of initiation]	NR
3.05.04.01.01	Summary	NR
3.05.04.01.02	Full Report	NR

3.05.04.01.03	Statistical Data	NR
3.05.05	Software/Firmware	NR
3.05.05.01	Software/Firmware Description	NR
3.05.05.02	Hazard Analysis	NR
3.05.05.03	Software Requirement Specification	NR
3.05.05.04	Architecture Design Chart	NR
3.05.05.05	Software Design Specification	NR
3.05.05.06	Traceability Analysis	NR
3.05.05.07	Software Development Environment Description	NR
3.05.05.08	Software Verification and Validation	NR
3.05.05.08.01	[Study description, study identifier, date of initiation]	NR
3.05.05.08.01.01	Summary	NR
3.05.05.08.01.02	Full Report	NR
3.05.05.08.01.03	Statistical Data	NR
3.05.05.09	Revision Level History	NR
3.05.05.10	Unresolved Anomalies (Bugs or Defects)	NR
3.05.05.11	Cybersecurity	NR
3.05.05.12	Interoperability	NR
3.05.06	Biocompatibility and Toxicology Evaluation	R
3.05.06.01	[Study description, study identifier, date of initiation]	R
3.05.06.01.01	Summary	R
3.05.06.01.02	Full Report	R
3.05.06.01.03	Statistical Data	R
3.05.07	Non-Material-Mediated Pyrogenicity	R
3.05.07.01	[Study description, study identifier, date of initiation]	R
3.05.07.01.01	Summary	R
3.05.07.01.02	Full Report	R
3.05.07.01.03	Statistical Data	R
3.05.08	Safety of Materials of Biological Origin (human/animal)	O
3.05.08.01	Certificates	O
3.05.08.02	[Study description, study identifier, date of initiation]	O
3.05.08.02.01	Summary	O
3.05.08.02.02	Full Report	O
3.05.08.02.03	Statistical Data	O
3.05.09	Sterilization Validation	NR
3.05.09.01	End-User Sterilization	NR
3.05.09.01.01	[Study description, study identifier, date of initiation]	NR
3.05.09.01.01.01	Summary	NR
3.05.09.01.01.02	Full Report	NR
3.05.09.01.01.03	Statistical Data	NR

3.05.09.02	Manufacturer Sterilization	NR
3.05.09.02.01	[Study description, study identifier, date of initiation]	NR
3.05.09.02.01.01	Summary	NR
3.05.09.02.01.02	Full Report	NR
3.05.09.02.01.03	Statistical Data	NR
3.05.09.03	Residual Toxicity	
3.05.09.3.01	[Study description, study identifier, date of initiation]	
3.05.09.3.01.01	Summary	
3.05.09.3.01.02	Full Report	
3.05.09.3.01.03	Statistical Data	
3.05.09.4	Cleaning and Disinfection Validation	NR
3.05.09.4.01	[Study description, study identifier, date of initiation]	NR
3.05.09.4.01.01	Summary	NR
3.05.09.4.01.02	Full Report	NR
3.05.09.4.01.03	Statistical Data	NR
3.05.09.5	Reprocessing of Single Use Devices Validation Data	NR
3.05.09.5.01	[Study description, study identifier, date of initiation]	NR
3.05.09.5.01.01	Summary	NR
3.05.09.5.01.02	Full Report	NR
3.05.09.5.01.03	Statistical Data	NR
3.05.10	Animal Testing	NR
3.05.10.01	[Study description, study identifier, date of initiation]	NR
3.05.10.01.01	Summary	NR
3.05.10.01.02	Full Report	NR
3.05.10.01.03	Statistical Data	NR
3.05.11	Usability/Human Factors	NR
3.05.11.01	[Study description, study identifier, date of initiation]	NR
3.05.11.01.01	Summary	NR
3.05.11.01.02	Full Report	NR
3.05.11.01.03	Statistical Data	NR
3.06	Non-clinical Bibliography	R
3.07	Expiration Period and Package Validation	R
3.07.01	Product Stability	R
3.07.01.01	[Study description, study identifier, date of initiation]	R
3.07.01.01.01	Summary	R
3.07.01.01.02	Full Report	R
3.07.01.01.03	Statistical Data	R
3.07.02	Package Validation	R
3.07.02.01	[Study description, study identifier, date of initiation]	R
3.07.02.01.01	Summary	R

3.07.02.01.02	Full Report	R
3.07.02.01.03	Statistical Data	R
3.08	Other non-clinical Evidence	NR
3.08.01	[Study description, study identifier, date of initiation]	NR
3.08.01.01	Summary	NR
3.08.01.02	Full Report	NR
3.08.01.03	Statistical Data	NR
CHAPTER 4 – CLINICAL EVIDENCE		
4.01	Chapter Table of Contents	NR
4.02	Overall Clinical Evidence Summary	NR
4.02.01	Clinical Evaluation Report	NR
4.02.02	Device Specific Clinical Trials	NR
4.02.02.01	[Trial description, protocol #, date of initiation]	NR
4.02.02.01.01	Clinical Trial Summary	NR
4.02.02.01.02	Clinical Trial Report	NR
4.02.02.01.03	Clinical Trial Data	NR
4.02.03	Clinical Literature Review and Other Reasonable Known Information	
4.03	IRB Approved Informed Consent Forms	NR
4.04	Investigators Sites and IRB Contact Information	NR
4.05	Other Clinical Evidence	NR
4.05.01	[Study description, study identifier, date of initiation]	NR
4.05.01.01	Summary	NR
4.05.01.02	Full Report	NR
4.05.01.03	Statistical Data	NR
CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL		
5.01	Chapter Table of Contents	R
5.02	Product/Package Labels	R
5.03	Package Insert/Instructions for Use	R
5.04	e-labelling	R
5.05	Physician Labelling	R
5.06	Patient Labelling	R
5.07	Technical/Operators Manual	R
5.08	Patient File Stickers/Cards and Implant Registration Cards	R
5.09	Product Brochures	R
5.10	Other Labelling and Promotional Material	R

CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES		
6A.01	Cover Letter	R
6A.02	Chapter Table of Contents	R
6A.03	Administrative	R
6A.03.1	Product Descriptive Information	R
6A.03.2	General Manufacturing Information	R
6A.03.3	Required Forms	R
6A.04	Quality management system procedures	R
6A.05	Management responsibilities procedures	R
6A.06	Resource management procedures	R
6A.07	Product realization procedures	R
6A.08	Design and development procedures	R
6A.09	Purchasing procedures	R
6A.10	Production and service controls procedures	R
6A.11	Control of monitoring and measuring devices procedures	R
6A.12	QMS measurement, analysis and improvement procedures	R
6A.13	Other Quality System Procedures Information	R
CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION		
6B.01	Chapter Table of Contents	R
6B.02	Quality management system information	R
6B.03	Management responsibilities information	R
6B.04	Resource management information	R
6B.05	Device Specific Quality Plan	R
6B.06	Product realization information	R
6B.07	Design and development information	R
6B.08	Purchasing information	R
6B.09	Production and service controls information	R
6B.10	Control of monitoring and measuring devices information	R
6B.11	QMS measurement, analysis and improvement information	R
6B.12	Other Device Specific Quality Management System Information	R

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