**WHO/-PQ-MD-PPE**

**PQS Performance specification**

Creation date:

Revision date:

Version no.

**Prequalification Program of Medical Devices-**

**Personal Protective Equipment;Medical Masks**

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| **SECTION 1 –ADMINISTRATIVE** | | | **COMMENTS** |
| **1.01** | **INTRODUCTION** | |  |
|  | This document describes the technical specification of medical masks which define the minimum requirements for the product to ensure good quality, safety and efficacy.  This document is based on the review of the WHO medical device technical series, the COVID-19 technical specifications for personal protective equipment, infection prevention and control (IPC) COVID-19 guidelines medical masks available in the market, medical masks approved by stringent regulatory agencies, and analysis of international, and regional standards on medical masks.  It includes discussion and comparison of alternative devices and standards to build consensus for shaping the global market. It is intended for regulators, policy-makers, programme managers, biomedical engineers, medical mask manufacturers and industries, procurement officers and health care providers. It should assist procurement agencies and regulatory authorities to prepare policy, management and supply accordingly. Manufacturers should comply with the technicalspecifications outlined as minimum requirements. This is to ensure that the medical mask have been designed, evaluated and validated consistent with these requirements to ensure it is safe and effective. | |  |
| **1.02** | **SCOPE** | |  |
|  | The purpose of this document is to provide technical guidance to medical device manufacturers that intend to seek WHO prequalification (PQ) of medical mask. This document specifies the technical specification PQ of medical mask for the following:  i) the scope of this publication will only focus on medical mask  ii) excluded medical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents and  iii) excluded reusable mask, respirator, community mask  The intended use of the medical mask is as follows:  i)used by healthcare workers (HCW)Type II medical mask and patient /community, Type 1 medical mask as a barrier to help protect them from liquid splashes and sprays, such as blood, that they may be exposed to during certain medical procedures.  ii) used to help capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria. (Source control)  The medical mask is to be used for the prevention of the transmission of air borne diseases or for infection prevention or reduction, including against SARS-CoV-2 and used in clinical, medical use, or use in other health services or in community settings | |  |
| **1.03** | **LIST OF ACRONYMS & ABBREVIATIONS** | |  |
|  | For the purposes of this document, the following terms and definitions apply. | |  |
|  | AQL: Acceptable quality limit | |  |
|  | BFE: Bacterial Filtration Efficiency | |  |
|  | PFE: Particulate Filtration Efficiency | |  |
|  | FFR: Filtering facepiece respirators | |  |
|  | IB: Barrier index | |  |
|  | ILAC International Laboratory Accreditation Cooperation | |  |
|  | IPC infection prevention and control | |  |
|  | PPE personal protective equipment | |  |
|  | RQL rejectable quality limit | |  |
|  | TAG PPE Technical Advisory Group of Experts on Personal Protective Equipment | |  |
|  | NIOSH National Institute for Occupational Safety and Health (USA) | |  |
|  | ISO International Organization for Standardization | |  |
|  | IEC: International Electrotechnical Commission | |  |
|  | ASTM; American Society for Testing and Materials | |  |
|  | SRA; Stringently regulated authority | |  |
|  | USFDA US Food and Drug Administration | |  |
|  | EU European Union | |  |
|  | CE: Conformité Européenne | |  |
|  | NMPA National Medical Products Administration (China) | |  |
|  | OSHA Occupational Safety and Health Administration (USA) | |  |
|  | FSCA: Field safety corrective action | |  |
|  | HDO; Healthcare Delivery Organisation | |  |
|  | GMDN:Global medical device nomenclature | |  |
|  | UMDNS:Universal medical device nomenclature system | |  |
|  | EPSP: Essential Principles Safety & Performance | |  |
|  | TGA: Therapeutic Goods Administration | |  |
|  | FSC free sales certificate | |  |
|  | WHO World Health Organization | |  |
| **1.04** | **LIST OF TERMS & DEFINITION** | |  |
|  | Medical mask  Medical masks are defined as d medical or procedure masks that are flat or pleated. They are affixed to the head with straps that go around the ears or head. Their performance characteristics are tested according to a set of standardized test methods (ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breathability and optionally, fluid penetration resistance (39, 40). | |  |
|  | Type 1 Medical Mask   |  |  |  | | --- | --- | --- | |  | Europe (EN 14683) | US (ASTM F2100) | | BFE | ≥ 95% | ≥ 95% | | PFE |  | ≥ 95% | | Pressure drop (Pa/cm2) | < 40Pa | < 49Pa or 5 mm H2O/cm2 | | Synthetic blood  penetration (kPa) | 120 mmHg (ISO 22609) | 80 mmHg or 10.7 kPa | | Microbial cleanliness  (CFU/g) | ≤ 30 N/A | ≤ 30 N/A | | |  |
|  | Type II Medical Mask   |  |  |  | | --- | --- | --- | |  | Europe (EN 14683) | US (ASTM F2100) | | BFE | ≥ 98% | ≥ 98% | | PFE |  | ≥ 98% | | Pressure drop (Pa/cm2) | < 60Pa | < 58.8 Pa or 6 mm  H2O/cm2 | | Synthetic blood  penetration (kPa) | 120 mmHg (ISO 22609)  16 kPa | 120 mmHg or 16 kPa | | Microbial cleanliness  (CFU/g) | ≤ 30 N/A | ≤ 30 N/A | | |  |
| **1.05** | **ESTABLISHMENT REQUIREMENTS**  Application Form/Administrative Information  The establishment who wishes to participate in the PQ of the medical mask shall comply with the following requirements | |  |
|  | Requirements | Description |  |
| **1.05.01** | Category of Establishment | Only legal manufacturer of the device |  |
| **1.05.02** | Name & Address of Organization | Manufacturing site |  |
| **1.05.03** | All manufacturing site(s), including the manufacturing site(s) is(are) a fully owned subsidiary(ies) or contractor(s) of the legal manufacturer. | Address |  |
| **1.05.04** | Responsible person and contact person of the legal manufacturer. | Name of responsible person |  |
| **1.05.05** | Quality Management System, Full Quality System or Other Regulatory Certificates | ISO13485:2016 or equivalent certified under the accreditation of an IAF MLA Signatory Accreditation Body  Validity: |  |
| **1.05.06** | Free Sale Certificate | |  |
| **1.05.07** | Marketing authorization | |  |
| **1.06** | **REQUIREMENTS FOR POST-MARKET SURVEILLANCE AND VIGILANCE** | |  |
| **1.06.01** | Complaint handling | The manufacturer shall establish and maintain procedures on management and handling of medical device complaints of the said devices in compliance with the importation country’s medical device regulation and policies |  |
| **1.06.02** | Distribution records | The manufacturer shall establish proper and effective procedure on managing and maintaining distribution records of the said devices in compliance with the importation country’s medical device regulation and policies |  |
| **1.06.03** | FSCA/FCA | The manufacturer shall establish proper and effective procedure on implementation of FCA in compliance with the importation country’s medical device regulation and policies |  |
| **1.06.04** | Recall | The manufacturer shall establish effective procedure on recall to describe actions to be taken in initiating and implementation of recall process timely and effectively to meet the requirements imposed by importation country’s medical device regulation and policies  The manufacturer shall monitor and notify the HDO and regulatory authority, advice user and facilitate removal of the mask from service, if required. |  |
| **1.06.05** | Mandatory problem/  adverse event reporting/  Incident reporting | The manufacturer shall ensure that all adverse event incidents pertaining to device failure and personal injury are investigated and reported to the HDO. The establishment shall carry out corrective and preventive actions to eliminate or reduce the risk of recurrence of incident.  The reporting shall comply with the importation country’s medical device regulation and policies. |  |
| **1.07** | **CHANGE NOTIFICATION** | |  |
|  | Manufacturer is to report planned future changes in product design specification, manufacturing location and manufacturing methods or ingredients to WHO | |  |
| **1.08** | **SUPPORT, TRAINING** | |  |
| **1.08.01** | Simple video on usage of medical mask | |  |
| **1.09** | **LISTING OF DEVICE(S)** | |  |
| **1.10** | **EXPEDITED REVIEW DOCUMENTATION** | |  |
| **1.11** | **USER FEES** | |  |
| **1.10** | **PRE-SUBMISSION CORRESPONDENCE AND PREVIOUS REGULATOR INTERACTIONS** | |  |
| **1.11** | **STATEMENTS/CERTIFICATIONS/DECLARATIONS OF CONFORMITY** | |  |
| **1.12** | **PERFORMANCE AND VOLUNTARY STANDARD** | |  |
| **1.13** | **TRUTHFUL AND ACCURATE STATEMENT** | |  |
| **1.14** | **DECLARATION OF CONFORMITY** | |  |

**SECTION 2 – SUBMISSION CONTEXT**

**2.0** **GENERAL SUMMARY OF SUBMISSION**

**The detail technical specification is listed in Table 1**

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| **SECTION 2 – SUBMISSION CONTEXT** | | **COMMENTS** |
| **2.01** | **GENERAL SUMMARY OF SUBMISSION**  **DEVICE DESCRIPTION**  Medical mask is fluid-resistant, medical device intended to be placed over the nose and mouth of a person, medical personnel or patients or public who are infected or displaying symptoms, to create a physical barrier between the mouth and nose of the wearer and prevent the transmission of fluid, spray and/or droplets during surgery or patient examination. Medical masks are graded as level 1, 2 or 3 based on the level of protection provided, including fluid resistance. |  |
| **2.02** | **DESCRIPTION OF DEVICE PACKAGING** |  |
| **2.03** | **INDICATIONS FOR USE AND/OR INTENDED USE AND CONTRAINDICATIONS**  **Intended use**  The intended use of the medical mask is as follow:  i)used by healthcare workers as a barrier to help protect them from liquid splashes and sprays, such as blood, that they may be exposed to during certain medical procedures.  ii) used to help capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria.  **Intended Environment/Setting for use**  *In the absence of aerosol generating procedures (AGPs, WHO recommends that health workers providing care to patients with suspected or confirmed COVID-19 should wear a medical mask* |  |
| **2.04** | **GLOBAL MARKET HISTORY** |  |
|  | i)Global Market History  This includes the list of regulatory approval or marketing clearance obtained including the registration status and status of any pending request for market clearance  ii)Global Incident Reports and Recalls  This includes important safety and performance-related information which includes summary of reportable adverse events/incident reports, recall and field corrective actions (FCAs)  iii)Sales, Incident and Recall Rates  iv)List of records on sales, incidents and rates.  v)Evaluation/Inspection Reports  vi)The last inspection reports |  |
| **2.05** | **SUMMARY AND CERTIFICATIONS FOR PREMARKET SUBMISSIONS** |  |
| **2.06** | **PRODUCT TECHNICAL SPECIFICATION** | Table 1 |

**TABLE 1: MEDICAL DEVICE TECHNICAL SPECIFICATION**

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| **MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*** | | | **COMMENTS** |
| i | Version No. | Ver2 |  |
| ii | Date of initial version | November 2020 |  |
| iii | Date of last modification | 1July 2022 |  |
| iv | Date of publication | TBD |  |
| v | Completed / submitted by | TBD |  |
| **NAME, CATEGORY AND CODING** | | |  |
|  | WHO Category / Code | (Under development) |  |
|  | Generic name | Medical Masks |  |
|  | \*GMDN name | Mask, medical, single use  medical/medical face mask, single-use  A flexible, loose-fitting mask designed to be placed over the mouth and/or nose of a healthcare worker to permit normal breathing while protecting the patient and wearer from the transfer of large particles (e.g., blood, body fluids, and airborne particulate materials) during medical procedures and patient examination; it is not a form-shaped filtering device (i.e., not a respirator). It is made of a flexible, porous fabric or paper material and is typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or transparent face/eye visor intended to protect the upper face/eyes from debris/fluid. This is a single-use device.  \*GMDN reference subject to copyright permission |  |
|  | GMDN code | 35177  Pending Copyright GMDN |  |
|  | GMDN category | Single use |  |
|  | UMDNS name | Mask, medical  Pending Copyright GMDN |  |
|  | UMDNS code | 12458  Pending Copy right UMDNS |  |
|  | UNSPS code (optional) | 42131606 |  |
| **PURPOSE OF USE** | | |  |
|  | Clinical or other purpose | The intended use of the medical mask is as follows:  i)used by healthcare workers and community as a barrier to help protect them from liquid splashes and sprays, such as blood, that may be exposed during certain medical procedures.  ii) used to help capture some particles and droplets expelled by the wearer, such as those that may contain viruses and bacteria.  \*Reference WHO |  |
|  | Clinical department/ward (if relevant) | **All areas, for infection prevention control (IPC)**  *In the absence of aerosol generating procedures (AGPs), WHO recommends that health workers providing care to patients with suspected or confirmed COVID-19 should wear a medical mask* |  |
|  | Overview of functional requirements | Medical mask shall protect both the patient and the HCW healthcare workers from the transfer of microorganisms, body fluids, and particulate material. |  |
| **TECHNICAL CHARACTERISTICS** | | |  |
|  | Detailed Parameters | Filtration: BFE & PFE  Fluid resistance  Pressure drop (Pa/cm 2)  Synthetic blood penetration (kPa)  Microbial cleanliness (CFU/g) |  |
| **TEST REPORT ORIGIN** | | |  |
| 13. | LAC accredited lab | Testing to be conducted by an accredited laboratory ISO 17025  Test methods based on the standards |  |
|  | National notifying body | ISO 17025:2017 |  |
|  | Local, non-accredited | ISO 17025:2017 |  |
| **MASK PERFORMANCE** | | |  |
| 14. | Materials used in medical face masks | ASTM F2100  Level 1,2,3 |  |
| 15. | Requirements and test methods for medical face masks | ASTM F2100/EN 14683 |  |
| 16. | Medical mask (fluid resistant) | ASTM F2100/EN 14683 |  |
| **PHYSICAL PERFORMANCE/CHARACTERISTICS** | | |  |
| 17. | Bacterial Filtration efficiency (3.0 μm particle size) | ASTM F2101/EN 14683 |  |
| 18. | Particle Filtration efficiency (0.1 μm particle size) | ASTM F2299 |  |
| 19. | Synthetic blood penetration | ASTM F1862 |  |
| 20. | Flammability | 16 CFR Part 1610 |  |
| 21. | Biocompatibility | ISO10993;2018 &  ISO10993:2021  **Refer to 3.03.04** |  |
| 22. | Basis weight | ASTM D3776 |  |
| 23. | Shelf life | 5 years |  |
| 24. | Specifications and Dimensions | • size  • dimensions  • tensile strength  • other specifications relevant to user needs, e.g., impact resistance |  |
| 25. | Pre COVID/Post COVID Design | TBD |  |
| **COMFORT CHARACTERISTICS** | | |  |
| 26**.** | Differential pressure | MIL-M-36945C 4.4.1.1.1  Method 1 or EN14683 |  |
| **QUALITY COMPLIANCE** | | |  |
| 27. | General quality  management system | ISO 9001:2015 |  |
| 28. | Medical device quality  management | ISO 13485;2016 |  |
| 29. | Sampling procedures for inspection by attribute | ISO 2859:2020 |  |
| **REGULATORY COMPLIANCE** | | |  |
| 30. | Proof of regulatory compliance, as appropriate, per the product’s risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]) |  |  |
| **PACKAGING** | | |  |
| 31. | Sterility status on delivery (if relevant) | Non-sterile. |  |
| 32. | Shelf life (if relevant) | Minimum shelf life for single-use medical mask must be 1 year from the date of reception. (5 years) |  |
| 33. | Transportation and storage (if relevant) | Storage environment humidity: 10–95% relative humidity. Storage environment temperature: –20 to 60 °C |  |
| 34. | Labelling (if relevant) | i)With the proper certification and validation requested, plus those required in each country  ii)Proposed labelling should be sufficient to describe the device, its intended use, and the directions for its use. (At least in English)  iii)UDI if available |  |
| **ENVIRONMENTAL REQUIREMENTS** | | |  |
| 35. | Context-dependent requirements | Handling environment temperature |  |
| 36. | Normal working conditions | Temperature: +5°C to +40°C  Relative Humidity: 15% to 90% |  |
| 37. | Storage conditions | Temperature: -20°C to +60°C  A relative humidity range of ≤ 93% |  |
| **WARRANTY** | | |  |
| 38. | Warranty |  |  |
| **DOCUMENTATION** | | |  |
| 39. | Documentation requirements | 1. Instruction for use must be available to the client, preferably in the national language(s) and/or in another language authorized by the national regulatory agency. 2. Test report 3. Contact details of manufacturer, supplier and local service agent to be provided. |  |
| **ESTIMATED LIFE SPAN** | | |  |
| 40. | Estimated Life Span | 5 years |  |
| **SAFETY AND STANDARDS** | | |  |
| 47. | Risk Classification | Class A (GHTF), Class I (Australia, Canada and Japan), Class IIa (EU), Class II (USFDA)USA |  |
| 48. | Marketing Approval  Status in other  country(-ies) | i)State the name (s) of country (ies)  ii) provide evidence such as Declaration of Conformity/ Device Licence/ Registration Certificate/510k) |  |
| 49. | Other requirement | The manufacturer shall issue a declaration letter stating that the equipment will not be discontinued within the next 5 years |  |

**SECTION 3 – NON-CLINICAL EVIDENCE**

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| **SECTION 3 – NON-CLINICAL EVIDENCE** | | | **COMMENTS** |
| **3.01** | **RISK MANAGEMENT** | i)Risk management report based on ISO14971;2019  ii)Risk analysis report  iii)Risk management plan |  |
| **3.02** | **ESSENTIAL PRINCIPLES (EP) /EPSP CHECKLIST** | The manufacturer shall Identify the Essential Principles that are applicable to the device and the general rule or method used to demonstrate conformity to each applicable Essential Principle. The rules or methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc. The specific documents related to the rule or method used to demonstrate conformity to the Essential Principles should be referenced in this element.  The evidence of conformity should be provided in tabular form called Essential Principles Conformity Checklist. |  |
| **3.03** | **STANDARDS** |  |  |
| **3.03.01** | Quality management systems | ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes or equivalent |  |
| **3.03.02** | Risk management | ISO 14971:2007 Medical devices – Application of risk management to medical devices |  |
| **3.03.03** | Recognized essential principles of safety and performance of medical devices  EPSP | ISO 16142-1:2016 |  |
| **3.03.04** | Biocompatibility | ISO 10993-1:2018 Biological Evaluation of Medical Devices and testing within a 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 |  |
| **3.03.05** | Information supplied by manufacturer | i)IEC980:2008  Information supplied by manufacturer  ii)EN1041:2008; Information supplied by the manufacturer of the medical devices |  |
| **3.03.06** | Symbols | ISO 15223-1:2021  Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements |  |
| **3.03.07** | Usability/Human Factors, | IEC 62366-1:2015 / EN 62366 Medical devices —  i)Part 1: Application of usability engineering to medical devices IEC 60601-6 (just added)  ii)Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability |  |
| **3.03.09** | Textiles | ISO 811:2018 Textiles - Determination of resistance to water penetration - Hydrostatic pressure test; |  |
| **3.03.10** | Medical face masks - Requirements and test methods | EN 14683:2019 Annex B &C  ASTM F2100-20 & 21 |  |
| **3.03.11** | Standard Specification for Performance of Materials Used in Medical Masks | EN 14683:2019 Annex B &C  ASTM F2100-20 & 21 |  |
| **3.03.13** | Clothing | ISO 22609:2004 Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected) |  |
| **3.03.17** | Sampling procedures for inspection | ISO2859-1:1999 |  |
| **3.03.18** | Performance of Materials Used in Medical Face Masks | ASTM F2100-19 |  |
| **3.03.19** | Flammability performance | CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles  CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles  i)NFPA Standard 702-1980: Standard for Classification of Flammability of Wearing Apparel 4  ii) UL 2154 |  |
| **3.03.20** | New standard: Barrier face covering | ASTM F3502-21 |  |
| **3.03.21** | Expiration Period and Package Validation | ISO 11607-1:2006 |  |
| **3.03.22** | Package Validation  General specifications and validation methods for non-sterile medical device packages in good distribution practice principles | ISO/DIS 23417 |  |

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| **SECTION 4 – CLINICAL EVIDENCE** | | | **COMMENTS** |
| **4.01** | **OVERALL CLINICAL EVIDENCE SUMMARY** | |  |
| **4.02** | **CLINICAL EVALUATION REPORT** | |  |
| **4.02.01** | Comparative study | |  |
| **4.02.02** | Clinical Literature Review and Other Reasonable Known Information | |  |
| **4.03** | **CLINICAL VALIDATION** | |  |
| **4.03.01** | Standard Test Method for Resistance of medical Mask to Penetration by Synthetic Blood. | ASTM F 1862 |  |
| **4.03.02** | Particulate Filtration Efficiency | ASTM F1215-89 |  |
| **4.03.03** | Bacterial Filtration Efficiency Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of medical masks | ASTM F2101 |  |
| **4.03.04** | To evaluate differential pressure (DELTA-P) TEST-USFDA | MIL-M-36945C 4.4.1.1.1 Method 1 Military Specifications: medical Mask, |  |

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| **SECTION 5 – LABELLING AND PROMOTIONAL MATERIAL** | | **COMMENTS** |
| **5.01** | **PRODUCT/PACKAGE LABELS**  Based on the local regulatory requirement (At least English) |  |
|  | Sample labels & packaging-QR code |  |
| **5.02** | **PACKAGE INSERT/INSTRUCTIONS FOR USE** |  |
| **5.03** | **E-LABELLING** |  |
| **5.04** | **PRODUCT BROCHURES** |  |
| **5.05** | **OTHER LABELLING AND PROMOTIONAL MATERIAL** |  |
| **SECTION 6A –QUALITY MANAGEMENT SYSTEM PROCEDURES** | | **COMMENTS** |
| **6A.01** | **PRODUCT DESCRIPTIVE INFORMATION** |  |
| **6A.02** | **GENERAL MANUFACTURING INFORMATION** |  |
| **6A.03** | **QUALITY MANAGEMENT SYSTEM PROCEDURES** |  |
| **6A.04** | **MANAGEMENT RESPONSIBILITIES PROCEDURES** |  |
| **6A.05** | **RESOURCE MANAGEMENT PROCEDURES** |  |
| **6A.06** | **PRODUCT REALIZATION PROCEDURES** |  |
| **6A.07** | **DESIGN AND DEVELOPMENT PROCEDURES** |  |
| **6A.08** | **PURCHASING PROCEDURES** |  |
| **6A.09** | **PRODUCTION AND SERVICE CONTROLS PROCEDURES** |  |
| **6A.10** | **CONTROL OF MONITORING AND MEASURING DEVICES PROCEDURES** |  |
| **6A.11** | **QMS MEASUREMENT, ANALYSIS AND IMPROVEMENT PROCEDURES** |  |
| **6A.12** | **OTHER QUALITY SYSTEM PROCEDURES INFORMATION** |  |
| **SECTION 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION** | |  |
| **6B.01** | **QUALITY MANAGEMENT SYSTEM INFORMATION** |  |
| **6B.02** | **MANAGEMENT RESPONSIBILITIES INFORMATION** |  |
| **6B.03** | **RESOURCE MANAGEMENT INFORMATION** |  |
| **6B.04** | **DEVICE SPECIFIC QUALITY PLAN** |  |
| **6B.05** | **PRODUCT REALIZATION INFORMATION** |  |
| **6B.06** | **DESIGN AND DEVELOPMENT INFORMATION** |  |
| **6B.07** | **PURCHASING INFORMATION** |  |
| **6B.08** | **PRODUCTION AND SERVICE CONTROLS INFORMATION** |  |
| **6B.09** | **CONTROL OF MONITORING AND MEASURING DEVICES INFORMATION** |  |
| **6B.10** | **QMS MEASUREMENT, ANALYSIS AND IMPROVEMENT INFORMATION** |  |
| **6B.11** | **OTHER DEVICE SPECIFIC QUALITY MANAGEMENT SYSTEM INFORMATION** |  |