## Product requirements:

### Author

|  |  |  |
| --- | --- | --- |
| Name / Title | Signature | Date |
|  |  |  |

### Approvals

**By signing below, the Project Team agrees that the requirements defined in the Product Specification are complete for the device, and that there are no ambiguous or conflicting requirements. Not all functions listed need sign. The CEO must sign.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Function** | **Name/Title** | **Signature** | **Date** |
| Project Management |  |  |  |
| Product Development |  |  |  |
| Manufacturing |  |  |  |
| Quality Assurance |  |  |  |
| Regulatory Affairs |  |  |  |
| Marketing |  |  |  |
| Clinical Affairs |  |  |  |
| CEO |  |  |  |

### Description of the Design

*<Provide any necessary background information and an overview of the product design.>*

### Definitions

*<Define any terminology related to the product, associated components, and intended use, if necessary.>*

### Requirements

*<The following design input categories are provided as a guide, however all requirements listed should be considered for each design project to ensure that the intended use of the device, including the needs of the user and patient are addressed. All categories shall be considered. Additional categories may be included, as required. If a particular category is not applicable or has been addressed in another section, you can either remove the category heading or indicate “Not Applicable” and include a brief explanation (, e.g., Sterility – Not Applicable, device is not sterile, Safety Characteristics – No additional requirements, addressed in items 3, 17, and 25, etc. The information in “<>” described below is to be used as guidance in completing the information and may be removed once the required information is documented.>*

### User Requirements

##### Indications for Use/Intended Use

*<A statement of the Indications for Use/Intended Use of the device including any product claims. This usually includes a general description of the disease or condition the device is intended to diagnose, treat, prevent, cure, or mitigate, and includes a description of the patient population for which the device is intended.>*

##### Duration of Use

*<Please check duration of use in terms of the invasiveness or non-invasiveness with particular emphasis on regulatory requirements below on product classification>*

##### Intended User

*<Requirements that address the anticipated knowledge, skills, experience, and judgment of the end user.>*

##### Human Factors (User, Patient)

*<Requirements based on the consideration of the interactions between the user and other elements of the system with the intent of producing a product that is easy to use and intuitive. Requirements related to the manner in which the device and the patient/user are intended to interact. Examples of this would be the various audible or visible alarms intended to alert the user to a hazardous condition, the layout of a control panel, or the mode of presentation of information to the user.>*

### Performance Requirements

*<The performance specifications of a device. Some examples of performance specifications are measurement accuracy, output accuracy, and energy output level.>*

##### Limitations and Tolerances

*<Boundary conditions for specifications and requirements.>*

##### Safety

*<Requirements intended to protect the end user from potential damage, errors, accidents or harm.>*

##### Reliability Requirements

*<The number of uses, time period, etc., over which the product is expected to perform successfully.>*

##### Shelf Life, Expiration Dating, and Stability Requirements

*<Lists any requirements that will keep the device or system free from change during its expected life.>*

##### Mechanical

##### Electrical

##### Energy Source

*<The type of power input to the device. Examples of energy sources are DC batteries, AC (Mains) power, etc.>*

### Functional Requirements

##### Physical Characteristics (i.e. size, shape, weight, dimension, markings, appearance)

##### Strength Requirements (i.e. torques, loading, threading)

##### Sensory Characteristics

##### Chemical Characteristics

##### Software Requirements

*<Design requirements for software and the functions that are affected by software. You may reference other software documentation in support of this requirement, as appropriate.>*

### Packaging and Labelling Requirements

*<Labelling requirements are requirements related to any written, printed or graphic material on the product, its container or wrapper, including warnings, precautions, contraindications, languages, etc. This may include user manuals, maintenance manuals, etc. Packaging requirements are any requirements related to any wrapping, containers, etc., used to protect, or to preserve the sterility of medical devices, including seal integrity requirements.>*

##### Packaging Configuration

##### Orientation Requirements

##### Seal Integrity Requirements

##### Ship Test Requirements

*<Define the requirements for shipping the product to include shipping configuration, package orientation during shipping, environmental influences, domestic vs international shipping, and transportation impact.>*

##### Label Requirements (i.e. color, size, location)

##### Warnings and Cautions

##### Language Requirements

##### Instructions for Use (IFU) Requirements

### Interface Requirements

##### Infield Calibration and/or Maintenance

##### Compatibility with Accessories and/or Auxiliary Devices

*<Lists any accessories and/or auxiliary devices that the device may be used with or attached to.>*

##### Compatibility with the Environment of the Intended Use

*<The ability of the device to operate in its environment of intended use. Examples include size and weight requirements for a portable device, waterproof, etc.>*

##### Electromagnetic Compatibility

*<Requirements related to a product’s ability to operate without causing electromagnetic interference (EMI) that would interfere with the operation of other equipment and without being affected by EMI from other equipment or the environment. May be addressed by referencing applicable standards.>*

### Biocompatibility, Toxicity and Sterility Requirements

##### Biocompatibility

*<List requirements that the device be biologically compatible by not producing toxic, injurious, or immunological response in living tissue.>*

##### Sterilization method

##### Sterility Requirements

*<Requirements on whether or not the device will be provided sterile. If sterile, possible requirements include those that address material, packaging and distribution issues, the sterility assurance level program requirements including acceptable levels of pyrogens, endotoxins, bioburden, and residual sterilant compounds, the method of sterilization, number of cycles, etc.>*

### Regulatory and Statutory Requirements

##### FDA / US Requirements

##### SOR 98-282 Canadian Requirements

##### Medical Device Directive (MDD) Annex

##### EMEA Requirements

*<Include any local or country specific requirements that may not be covered by US, if any.>*

##### Rest of World Requirements

*<Include any local or country specific requirements that may not be covered by US or EMEA, if any.>*

### Environmental Requirements

*<The (range of) acceptable levels of environmental parameters or operating conditions under which the device will perform safely and effectively. This may include operating and storage temperatures and humidity, etc.>*

##### Temperature (Storage, Shipping, Operating)

##### Humidity (Storage, Shipping, Operating)

##### Disposal Requirements

### Manufacturing Requirements

*<Requirements that take into consideration or are related to manufacture of the device.>*

### References, Statutory or Regulatory Requirements, and Standards

*< Provide a list of all documents and other sources of information referenced in this document and utilized in its development. Include for each the document number, title, date, and responsible office/author. This should describe those references that are indicated throughout section 3 of the Product Specification.>*

|  |  |  |
| --- | --- | --- |
| Standard / Regulation | Title / Description | Date of issue / publication / release |
| **Specification, performance and manufacture** | | |
| ISO 16142-1:2016 | Medical devices. Recognized essential principles of safety and performance of medical devices. Part – 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards |  |
| IEC 60601-1 | Basic safety and essential performance |  |
| ISO 14644-1 | Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness |  |
| IEC 60601-1-6 | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability |  |
| IEC 62366-1:2015 | Medical devices -- Part 1: Application of usability engineering to medical devices |  |
| **Safety and biocompatibility** | | |
| BS EN ISO 10993-1:2009 | Biological evaluation of medical devices. Evaluation and testing within a risk management process |  |
| BS EN ISO 10993-3:2014 | Biological evaluation of medical devices. Tests for genotoxicity, carcinogenicity and reproductive toxicity |  |
| BS EN ISO 10993-5:2009 | Biological evaluation of medical devices. Tests for in vitro cytotoxicity |  |
| BS EN ISO 10993-10:2013 | Biological evaluation of medical devices. Tests for irritation and skin sensitization |  |
| BS ISO 18562-1:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications. Evaluation and testing within a risk management process |  |
| BS ISO 18562-2:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of particulate matter |  |
| BS ISO 18562-3:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of volatile organic compounds (VOCs) |  |
| BS ISO 18562-4:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for leachable in condensate |  |
| **Labelling and Instruction for use.** | | |
| EN 980 | Graphical symbols for use in the labelling of medical devices |  |
| BS EN ISO 1041 | Information supplied by the manufacturer of medical devices |  |
| ISO 7000 | Graphical symbols for use on equipment — Index and synopsis |  |
| ISO 15223-1:2016 | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements |  |
| ISO 15223-2:2010 | Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Symbol development, selection and validation |  |
| **Risk management** | | |
| ISO 14971:2012 | Medical devices – Application of risk management to medical devices |  |
| ISO 14155:2011 | Clinical investigation of medical devices for human subjects – Good clinical practice |  |
| ISO 80601-2-13 | Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anesthetic workstation |  |
| ISO 80601-2-70 | Medical Electrical Equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment |  |
| ISO 80601-2-74 | Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment |  |
| BS IEC 62366:2007 | Medical devices -- Application of usability engineering to medical devices |  |
| ISO 8185:2007 | Respiratory tract humidifiers for medical use- particular requirements for respiratory humidification systems (parts applicable to breathing tubes) |  |
| **Testing standards** | | |
| ASTM F1054-87 | Standard Specification for Conical Fittings |  |
| ASTM F1054-01 | Standard Specification for Conical Fittings (Withdrawn 2005) |  |
| ASTM F1980 | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices |  |
| **Applicable global regulations** | | |
| EU – MDR | Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)  ***See Annex-I: General Safety and Performance Requirements*** | DOP-05/05/2017  DOA-26/05/2020 |
| EMC | EU Commission directive – 2004/108/EC  *Electromagnetic compatibility* |  |
| WEEE | Directive 2002/96/EC and 2012/19/EU  *Waste Electrical and Electronic Equipment* |  |
| RoHS | Directive 2002/95/EU and 2011/65/EU  *RoHS (Restriction of Hazardous Substances, collateral to UK CoSHH instrument)* |  |
| LVD¶ | Directive 2006/95/EC  ¶Low voltage directive |  |
| Animal derived tissues | EU Reg. No. 722/2012 |  |
| Human blood derivatives | EU Commission Directive 2000/70/EC – Not applicable[[1]](#footnote-1) |  |
| Medicinal substances | EU Commission Directive 2001/83/EC – Not applicable2 |  |
| Personal Protective Equipment (PPE) | EU Commission Directive 89/686/EEC – Not applicable2 |  |
| Pressurised equipment | EU Commission Directive 2014/68/EEC – Not applicable2 |  |
| Machinery | EU Commission Directive 2006/42/EC – Not applicable2 |  |
| United States of America |  |
| 21 CFR §Part 11 | Electronic Records / Electronic Signatures |  |
| 21 CFR §Part 801 | Labelling |  |
| 21 CFR §Part 803 | Medical Device Reporting |  |
| 21 CFR §Part 806 | Medical Devices; Reports of Corrections and Removals |  |
| 21 CFR §part 814 | Premarket approval of medical devices (510(k)/PMA) |  |
| 21 CFR §Part 820 | Quality System Regulation |  |
| 21 CFR §886.4350 | Part 886 – Ophthalmic devices  Sec. 868.4350 Manual ophthalmic surgical instrument  ***(a) Identification****. A manual ophthalmic surgical instrument is a nonpowered, handheld device intended to aid or perform ophthalmic surgical procedures. This generic type of device includes the manual corneal burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilator, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotomy probe, cornea-sclera punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome or ophthalmic manual trephine.*  ***(b) Classification****. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 886.9.*  *[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994; 60 FR 15872, Mar. 28, 1995; 66 FR 38813, July 25, 2001]* |  |
| Canada |  |  |
| SOR 98-282 | CMDR, Canadian Medical Device Regulation |  |

### Glossary

*<Define of all terms and acronyms required to properly interpret the requirements contained within this document.>*

### Appendices

*<Include any relevant appendices (deliverables / reports/ documents as part of the process study).>*

1. The mentioned regulatory instrument is not applicable to Organisation – Medical Device Software. [↑](#footnote-ref-1)