American National Standard

ANSI/AAMI/ISO 15676:2016

Cardiovascular implants and artificial organs—Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

Cardiovascular implants and artificial organs—Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

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AAMI

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American National Standards Institute

Abstract: Specifies requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO). Applicable to all medical tubing intended for cardiopulmonary bypass (CPB) and/or extracorporeal membrane oxygenation (ECMO), but specific requirements and tests are included for tubing intended for use with peristaltic pumps during (short-term, i.e. <6 h duration) CPB surgery or (long-term, i.e. >24 h) ECMO procedures. Sterility and non-pyrogenicity provisions of this document are applicable to tubing packs labelled as “sterile”.

Keywords: biocompatibility, connections, filtration, flow, pyrogenicity, sterility

AAMI Standard

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Blood/Gas Exchange Device Committee

The adoption of ISO 15676:2016 as an American National Standard was initiated by the AAMI Blood/Gas Exchange Device Committee. The AAMI Blood/Gas Exchange Device Committee also functions as the U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Blood/Gas Exchange Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Blood/Gas Exchange Device Committee** (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4) had the following members:

Cochairs:	Trevor Huang, PhD MBA
	Mark Kurusz, CCP
Members:	Richard Chan, CCP, Northshore University Hospital
	Drew Holmes, Baxter Healthcare
	Tsuyoshi Hosoi, Terumo Cardiovascular Systems
	Trevor Huang, PhD MBA, Medtronic Perfusion Systems
	George Silvay, MD PhD, Mount Sinai Medical Center
	Catherine Wentz, FDA/CDRH
Alternates:	David M. Fallen, CCP, Terumo Medical
	Qijin Lu, FDA/CDRH
	Rakesh Sethi, Medtronic

NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO 15676:2016

As indicated in the foreword to the main body of this document (page vii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee (TC) 150 Subcommittee (SC) 2, *Cardiovascular implants and extracorporeal systems,* to ensure that medical grade tubing in single-use tubing packs for the transfer of blood and fluid during the period of cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) is adequately tested for both safety and function.

U.S. participation in this ISO SC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI).

AAMI encourages its committees to harmonize their work with international standards as much as possible. The U.S. adoption of ANSI/AAMI/ISO 15676:2016 was approved by the American National Standards Institute (ANSI) on 18 November 2016. The AAMI Blood/Gas Exchange Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4, Blood/gas exchangers) initiated the U.S. adoption of ISO 15676:2016.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 15676:2016.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 15676:2005), which has been technically revised.

Introduction

The intent of this document is to ensure that medical grade tubing in single-use tubing packs for the transfer of blood and fluid during the period of cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) is adequately tested for both safety and function. The user commonly provides the specifications for the tubing pack. Furthermore, the purpose of this document is to ensure that the tubing pack characteristics be appropriately disclosed in the labelling and manufacturing information package. Tubing performance characteristics are specifically addressed within the context of this document as a component part of a single-use tubing pack.

This document therefore contains recommended procedures to evaluate such medical grade tubing intended for use during CPB procedures and ECMO. Test procedures to determine the material characteristics, the useful life of the tubing when used in a roller pump, and cleanliness are described. The limits for these characteristics are not specified.

This document also includes minimum reporting requirements. Ready identification of the performance characteristics should assist the user in the selection of such medical grade tubing for the procedure appropriate to the patient and procedure. This information may be useful in a clinic's quality control process that aims to improve the safety of CPB and ECMO procedures.

This document makes reference to other International Standards, which references methods for the determination of characteristics common to medical devices.

Requirements for animal and clinical studies are not included in this document. Such studies, however, may be part of a manufacturer's quality system.

This document contains only those requirements that are specific to such medical grade tubing for use during CPB and ECMO. Non-specific requirements are covered by reference to other International Standards listed in the Normative References section.

Cardiovascular implants and artificial organs—Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

1 Scope

This document specifies requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO). This document is applicable to all medical tubing intended for cardiopulmonary bypass (CPB) and/or extracorporeal membrane oxygenation (ECMO), but specific requirements and tests are included for tubing intended for use with peristaltic pumps during (short-term, i.e. <6 h duration) CPB surgery or (long-term, i.e. >24 h) ECMO procedures. The sterility and non-pyrogenicity provisions of this document are applicable to tubing packs labelled as “sterile”.

This document is applicable only to the tubing aspects for multifunctional systems that may have integral components such as blood gas exchangers (oxygenators), reservoirs, blood filters, defoamers, blood pumps, etc.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 34-1, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 527-1, Plastics — *Determination of tensile properties — Part 1: General principles*

ISO 9352, Plastics — *Determination of resistance to wear by abrasive wheels*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ASTM D792-00, *Standard test methods for density and specific gravity (relatively density) of plastics by displacement*

ASTM D2240-04, *Standard test method for rubber property — Durometer hardness*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
durometer hardness
measure of hardness of elastic materials by Shore A range

3.2
elongation
increase in linear dimension

3.3
tensile strength
force per unit of original cross section on *elongation* (3.2) to rupture

3.4
tear strength
measure of stress needed to continue rupturing a sheet of rubber or plastic, usually after an initial cut

3.5
tubing pack
consists of tubing sections joined by extracorporeal connectors and/or connected to extracorporeal devices intended for CPB or ECMO applications

3.6
specific gravity
ratio of the mass of a body to the mass of an equal volume of water at 4 °C

3.7
spallation
phenomenon whereby particles dislodge from a surface under cyclical stress

3.8
brittle point
temperature at which 50 % of test samples exhibit cracking or breakage after linear impact at a specified speed

3.9
blood analogue
test solution which simulates blood viscosity between 2.0×10^{-3} Pa·s (2.0 cP) to 5.0×10^{-3} Pa·s (5,0 cP)

Note 1 to entry: The higher viscosity specified addresses conditions encountered during a range of clinical procedures specific to the tubing pack.

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The blood pathway shall be sterile and non-pyrogenic. Compliance shall be verified in accordance with 5.2.1.

4.1.2 Biocompatibility

All parts of the tubing pack that may come in direct contact with the patient's blood pathway shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 General

When tested in accordance with 5.3.1, the blood pathway shall not leak.

4.2.2 Dimensions

The dimensions of the tubing (e.g. inner diameter, wall thickness, segment lengths) shall conform to the specifications of the user.

4.2.3 Material properties

The tubing material shall be tested or specified by the manufacturer or extruder to determine that the material properties listed in this subclause conform to the manufacturer's specifications as reported in 6.4 b). Upon request, the manufacturer should make them available in a technical data sheet. The material properties include the following:

a) durometer hardness;

b) ultimate elongation;

c) tensile strength;

d) brittle point;

e) specific gravity;

f) tear strength.

4.3 Performance characteristics

4.3.1 Priming volume

The priming volume shall be measured or calculated and reported in 6.2 e). Results shall indicate the priming volume over the entire range of tubing size provided by the manufacturer. Testing shall be performed according to the manufacturer's protocol.

Some of these tests may be combined and performed at the same time.

4.3.2 Life to failure testing

The labelled anticipated lifetime of the roller pump boot tubing should be a figure not exceeding the lifetime of tubing as determined using the test specified in 5.4.1. The tubing shall be tested under the operating variables specified by the manufacturer in 6.2 c) for each available size and wall thicknesses of tubing. The results of these tests shall be reported as mean and standard deviation in 6.3 d).

4.3.3 Spallation

When tubing intended for use in a peristaltic pump is tested in accordance with 5.4.2, the spalled particles shall not exceed the level specified by the manufacturer.

4.3.4 Shelf life

When tested in accordance with 5.4.3, test results shall demonstrate the rated shelf life as specified by the manufacturer.

5 Tests and measurements

5.1 General

5.1.1 Tests and measurements shall be performed with the device under test prepared according to the manufacturer's instructions for intended clinical use.

5.1.2 Operating variables shall be those specified by the manufacturer for intended clinical use, unless otherwise specified.

5.1.3 According to the intended clinical use of the tubing, the temperature of test liquids shall be 4 °C, 30 °C and 39 °C, or other temperatures to reflect typical and extreme use conditions.

5.1.4 If the relationship between variables is nonlinear, sufficient determinations shall be made to permit valid interpolation between data points.

5.1.5 The test or measurement procedures are to be regarded as reference procedures. Other procedures can be accepted provided that the alternative procedure has been shown to be of comparable precision and reproducibility.

5.2 Biological characteristics

5.2.1 Sterility and non-pyrogenicity

Sterility and non-pyrogenicity shall be determined in accordance with the requirements of ISO 17665-1, ISO 11135, ISO 11137-1, ISO 11137-2 and ISO 14937, as applicable.

5.2.2 Biocompatibility

Biocompatibility shall be determined in accordance with the requirements of ISO 10993-1 and ISO 10993-11. If the product is sterilized with ethylene oxide, biocompatibility shall also be tested in accordance with the requirements of ISO 10993-7.

5.3 Physical characteristics

5.3.1 Blood pathway integrity

5.3.1.1 The test shall be performed at 37 °C with air or water at the appropriate pressures. The test shall be performed to ensure freedom from leaking.

5.3.1.2 Subject the tubing to a positive pressure of 1,5 times the manufacturer's rated pressure or, if no maximum pressure is specified, the test shall be performed at 152 kPa for 6 h or as long as it is specified by the manufacturer for clinical use. Using air pressure decay or visual inspection, check for leakage.

5.3.2 Connections

The connections shall withstand a pull force of 15 N for 15 s without separating. Testing shall be performed as specified in the manufacturer's protocol.

5.3.3 Tubing material property testing

Tubing material property testing shall be determined in accordance with the requirements of ISO 34-1, ISO 527-1, ISO 9352, ASTM D792-00, and ASTM D2240-04, as applicable or consistent with the requirements of the end user.

5.4 Performance characteristics

5.4.1 Tubing life

5.4.1.1 The test liquid shall be a blood analogue to simulate blood viscosity.

5.4.1.2 The manufacturer shall conduct the test with a conventional dual-roller pump, reservoir, tubing, measurement and control equipment specified by the manufacturer. Tubing of each internal diameter and wall thickness shall be tested. The operating variables of pump speed, back pressure, liquid temperature, and method of setting pump occlusion shall be described, monitored and kept constant over the course of the test.

5.4.1.3 A failure is a leak in the tubing wall.

5.4.2 Spallation in tubing used in roller pumps

5.4.2.1 The test circuit should incorporate two Y-connectors to accommodate a bypass that includes a fine filter to collect particles by circulating the entire test circuit volume in such a manner that all fluid is diverted through the filter.

5.4.2.2 The test liquid shall be glycerine solution to simulate blood viscosity and the test shall be conducted at temperatures intended for clinical use, pre-filtered through a 5 µm filter.

5.4.2.3 The minimum volume of fluid in the circuit shall be provided and actual volume contained at test onset shall be reported.

5.4.2.4 The flow rate(s) shall be reported, so that the volume/hour of fluid contacting the tubing wall can be estimated, as in accepted methods for quantifying wear debris generation.

5.4.2.5 The filter should be removed at the appropriate time point (e.g. 1 h, 2 h, or longer depending on specific application such as CPB or ECMO as described in 5.4.2.7) assuring that all the liquid contained in the circuit has passed through the filter at least once and a new filter inserted for the next time period. Removed filters shall be dried and weighed and values recorded. In this manner, there will be minimal volume depletion of the total circulating volume.

5.4.2.6 The manufacturer shall test tubing of each internal diameter and wall thickness with the test equipment described in 5.4.1.2.

5.4.2.7 The circuit shall be run for 1 h intervals with the longest test lasting 6 h. For CPB, the circuit shall be sampled at 1 h, 2 h, 4 h, 6 h and for ECMO circuits, at least every 24 h thereafter for the length of time specified by the manufacturer.

5.4.2.8 The cumulative mass of spall particles shall be reported in milligrams recovered for each time point.

5.4.3 Shelf life

Using a validated method, ageing should be performed on final, finished, sterilized, devices in primary packaging in order to determine nominal shelf life.

6 Information supplied by the manufacturer

6.1 Information on the tubing pack

6.1.1 Information on the unit container

The following shall be given on the unit container:

a) the manufacturer's name and address;

b) the description of contents;

c) the model designation;

d) the statement on sterility and non-pyrogenicity;

e) the batch, lot or serial number designation;

f) the statement “read instructions before use” or equivalent symbol;

g) the special handling or storage conditions;

h) the statement on single-use;

i) the expiry date.

6.1.2 Information on the shipping container

The following shall be provided on the shipping container:

a) the manufacturer's name and address;

b) the description of contents, including number of units;

c) the model designation;

d) the statement on sterility and non-pyrogenicity;

e) the special handling, storage or unpacking instructions;

f) the batch, lot or serial number.

6.2 Information on the accompanying documents

Each shipping container shall contain an “Instructions for use” leaflet with the following information:

a) the manufacturer's address and telephone number (fax number and internet site address optional);

b) the model designation;

c) the operating instructions;

d) the placement, type and securing of tubing connections;

e) the volume per length for all sizes of tubing;

f) the pressure limitations for blood pathways;

g) the statement that the following are available upon request:

   1) sterilization method;

   2) list of the materials of the blood pathway.

6.3 Information in the accompanying documents in a prominent form

The following information shall be provided in a prominent form in the accompanying documents:

a) the inner diameter and wall thickness;

b) the pressure limitations;

c) the flow rate limitations;

d) the expected life under manufacturer's operating conditions, reported as mean and standard deviation;

e) the other device limitations, e.g. material incompatibility with known volatile anaesthetic agents, solvents, or disinfectants.

6.4 Information to be provided by manufacturer upon request

The following information shall be provided by the manufacturer upon request:

a) the results of the testing conducted under 5.3.3;

b) the physical characteristics (cited in 4.2.3);

c) the spallation data.

7 Packaging

Packaging shall comply with the appropriate requirements of ISO 11607-1 and ISO 11607-2.

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