

Technical Information Report

AAMI/ISO TIR17665-3: 2014/(R)2016

Sterilization of health care
products—Moist heat—
Guidance on the
designation of a medical
product to a product family
and processing category
for steam sterilization

Sterilization of health care products—Moist heat— Guidance on the designation of a medical product to a product family and processing category for steam sterilization

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Abstract: This Technical Specification provides guidance about the attributes of a medical device to be considered by the user when assigning a medical device to a product family for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process.

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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.

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Committee representation

Association for the Advancement of Medical Instrumentation Radiation Sterilization Working Group

The adoption of ISO Technical Specification (TS) 17665-3, as an AAMI Technical Information Report was initiated by the AAMI Radiation Sterilization Working Group, which 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 Industrial Moist Heat Sterilization Working Group (U.S. Sub-TAG for ISO/TC 198/WG 3, Industrial Moist Heat Sterilization) played an active role in developing the ISO Technical Specification.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

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

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Background of AAMI adoption of ISO/TS 17665-3:2013

AAMI/TIR 17665-3 is an identical adoption of ISO/TC 17665-3.

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 that 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 document 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 document 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 xi, this AAMI TIR is identical to ISO/TS 17665-3:2013.

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. www.iso.org/directives

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The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

ISO 17665 consists of the following parts, under the general title *Sterilization of health care products — Moist heat*:

- *Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*
- *Part 2: Guidance on the application of ISO 17665 Part 1: 2006 [Technical Specification]*
- *Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization [Technical Specification]*

Introduction

The type of moist heat sterilization process used to successfully process a medical device is identified from the physical, design, material and functional characteristics of the medical device and any sterile barrier system and/or packaging system used to present the medical device for sterilization.

Manufacturers of moist heat sterilizers may supply sterilizers with a number of pre-set sterilization processes. These pre-set sterilization processes may be suitable for sterilizing a wide range of medical devices or combinations of medical devices; however, there may be a need to develop customized sterilization processes to sterilize medical devices or combinations of medical devices that pose a particular challenge to the pre-set sterilization processes.

The designs and nature of materials used to construct medical devices are increasing in complexity. Materials used in the manufacture of sterile barrier systems and/or packaging systems and the combinations of different medical devices in procedure sets can adversely affect conductivity, air removal and moist heat penetration, causing a failure to obtain the required sterility assurance level.

The classification of a medical device into a product family can assist with the development of moist heat sterilization process conditions for this medical device. Assigning a medical device to a particular product family is the first stage of performance qualification at the point of use as specified in ISO 17665-1 and ISO/TS 17665-2. The efficacy of sterilization for a medical device using the sterilization process for that product family should be assessed and documented together with any pre-treatments, such as cleaning, disinfection to reduce bioburden followed by lubrication and humidification of some materials e.g. those containing cellulose.

In this part of ISO 17665 the attributes which relate to efficient sterilization and which are used to identify a product family have been selected from operational experience, engineering considerations and experimental data relating to the efficacy of the different types of moist heat sterilizers and their sterilization processes, and the types and design of differing medical devices and sterile barrier systems and/or packaging systems. Medical devices that are labelled by the manufacturer as being capable of being sterilized via moist heat may be categorized into product families by a user. However, not all medical devices will fit into one of the product families described in this part of ISO 17665. In these cases, new product families will need to be identified based on the consideration of the products attributes and require additional performance qualification.

Medical devices that have been classified into different product families are often processed in the same sterilization load when assembled into a randomly selected load configuration. This approach is common and acceptable in health care facilities where it is generally not feasible to qualify each sterilization load, provided that the sterilization process and sterilizer have been shown to be capable of sterilizing the range of product families constituting the sterilization load. Care should be taken to ensure that the combination of product families does not create a greater sterilization challenge than that set by the individual product families. In addition, consideration should be given to possible adverse interactions between medical devices such as the contamination of instruments with textile fibres. The examples shown in Annex B and D are illustrations of how the coding system is intended to be used in developing a sterilizer load.

This part of ISO 17665 should be read in conjunction with ISO 17665-1 and ISO/TS 17665-2.

Sterilization of health care products—Moist heat— Guidance on the designation of a medical product to a product family and processing category for steam sterilization

1 Scope

This part of ISO 17665 provides guidance about the attributes of a medical device to be considered by the user when assigning a medical device to a product family for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process.

NOTE While this part of ISO 17665 is applicable to health care facilities, it may be used by a manufacturer of a sterile medical device and/or whenever information on reprocessing is required (see ISO 17664).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 17665-1 and the following apply.

3.1

master product

medical device or procedure set used to represent the most difficult to sterilize item in a product family or processing category

3.2

processing category

collection of different products or product families that can be sterilized together

3.3

steam penetration resistance

challenge to a sterilization process from a medical device, including any sterile barrier/packaging system that may delay attainment of the process parameters for moist heat sterilization on all parts of the medical device

3.4

user

responsible body, which can be an individual or group, accountable for ensuring products are sterilized and suitable for intended use

4 Classification

Each medical device, whether new or modified, should be classified using the general attributes listed in Table 1. Specific characteristics of a medical device should, as applicable, be identified from the subclauses detailed in 4.2.

NOTE 1 Requirements for information to be provided by the manufacturer for the reprocessing of resterilizable medical devices are given in ISO 17664.

If a collection of medical devices are to be contained in a sterile barrier system and/or packaging system e.g. a procedure set, the challenge to the sterilization process from each medical device should be rated relative to the other medical devices as described in this part of ISO 17665. The product family assigned to this collection should be determined by the medical device which presents the greatest challenge to the sterilization process and the sterile barrier system and/or packaging system used. This product family will enable an appropriate processing category and sterilization process to be selected. The combination of the device with the highest rating and the chosen sterilization process should be subject to qualification in accordance with ISO 17665-1.

NOTE 2 Requirements and guidance for sterile barrier systems and packaging systems may be found in ISO 11607 (all parts) and EN 868 (all parts).

Some combinations of physical characteristics, such as those specified in Table 1, may cause an unpredictable adverse change to the steam penetration resistance as illustrated in Table 6. This can lead to an underestimation of the difficulty to sterilize (see Clause 5, Example 2). In such situations performance qualification should always be carried out in accordance with ISO 17665-1.

4.1 General attributes

Table 1 — General attributes

Attribute	Code
Design	a
Weight	b
Material	c
Sterile barrier system	d

4.2 Detailed attributes

The following attributes provide detail for characterizing a medical device and a sterilization process. Increased resistance to steam penetration is indicated by ascending code numbers.

Some attributes will be specified by the manufacturer of the medical device and others by the user. The manufacturer of a medical device will usually specify the attributes needed by the user to assess its steam penetration resistance and to select a processing category for a specific sterilizer and sterilization process. Both the resistance and the category should be reassessed when the medical device is to be combined with others in a sterile barrier system and/or packaging system.

The sterilization process should be qualified to verify that the required lethality will be delivered to all medical devices processed together (see ISO 17665-1 and ISO/TS 17665-2).

4.2.1 Design

For the purpose of identifying a type of sterilization process for reprocessing and assigning a processing category, a medical device should be broadly identified from one or more of the designs described in Table 2. The steam penetration resistance will be different for each design when air is to be removed and replaced by saturated steam. The following should be considered when developing an air removal process.

a1: air is displaced predictably as temperature rises with the introduction of steam. This action is unlikely to be affected by orientation.

a2: instrument may need to be in an open position and an active air removal process may be necessary.

a3: residual air in hollows may cause unpredictable delays to sterilizing conditions. Defined orientation and/or the dilution of air by an active air removal process may be necessary.

a4: inadequate removal of air during the air removal stage of the sterilization process can cause uncertainty in the attainment of sterilizing conditions.

a5: an active air removal process will be required. Condensate resulting from temperature differences within materials, interaction between adjacent medical devices and the quality of steam can cause an adverse effect on the efficiency of air dilution.

a6: an active air removal process will be required. Condensate can cause occlusion, inadequate air removal and inadequate steam penetration.

a7: if an active air removal process is required, develop the sterilization process to the product.

Table 2 — Design

Structure	Code (a)	Example
Solid, hollow	1	Bowl, jug, dish, bottle, chisel, single piece skin retractor, single component empty instrument tray
Pin and box joints	2	Scissor, forceps, needle holder
Lumen	3	Laparoscopic sheath, sucker, cannulated reamer, rigid endoscope, cannulated screws
Porous	4	Linen, filters, gauze
Tubing, moving parts, tortuous paths	5	Power tool hose, silicone tubing, dental hand piece, ear nose throat drill,
Lumen surrounded by a large mass	6	Drill, cannulated screw driver, obturator, ratchet handle, bored handle
Other	7	Pre-filled syringe

4.2.2 Material

The materials used to manufacture a medical device will be either metallic or non-metallic or a combination of both. Typically, metallic materials will have a high thermal conductivity and non-metals will have low thermal conductivity.

Materials with low thermal conductivity exhibit higher temperature differences throughout the material when compared to materials with high thermal conductivity. Both types of material present challenges to the sterilization process. The moisture content of the material may also influence the heat transfer into the product. This should be taken into account during performance qualification with the material in its most challenging state.

When compared to materials with low thermal conductivity, materials with high thermal conductivity and equal heat capacity will:

- initially generate more condensate in a given time period,
- absorb and release energy faster,
- attain a state of equilibrium faster.

Examples of some of the materials used are shown in Table 3.

Table 3 — Materials

Material	Example material	Code (b)
Metal	Stainless steel, carbon steel copper and copper-based alloys. Other metals or combinations of metal.	1
Non-metal	Glass, cellulose, polycarbonate, PVC, PTFE, silicon. Other non metals.	2

4.2.3 Weight

The weight of a medical device, or part of a medical device (if processed separately), or for a collection of medical devices grouped into a single sterile barrier system and/or packaging system, should be assigned to one of the codes indicated in Table 4. This information may be required when judging:

- heat-up time;
- cooling time/drying time;
- exposure time in a mixed weight sterilizer load;
- the stability of a single or composite construction material;
- the amount of condensate and its effect on steam penetration.

Table 4 — Weight

Weight g	Code (c)
Less than 50	1
50 to 499	2
500 to 1999	3
2000 and greater	4

4.2.4 Sterile barrier system and/or packaging system

Except when a medical device is to be presented aseptically immediately after being re-processed, it will be contained in a sterile barrier system and/or packaging system prior to it being sterilized [see ISO 11607 (all parts) for code d2 to d4 in Table 5]. When establishing the steam penetration resistance and moisture retention for a medical device or a collection of medical devices, the influence on the combined steam penetration resistance caused by the system and the materials used in its construction should be known. A collection of sterile barrier systems and /or packaging systems are listed in Table 5.

NOTE 1 In some countries local regulations may forbid the sterilization of unwrapped medical devices, in which case code d1 would not apply.

Table 5 — Sterile barrier system and/or packaging system

Sterile barrier system	Code (d)
None	1
Single wrapped/pouch	2
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturers instructions	3
Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system	4

NOTE 2 Information on the intended use of the sterile barrier systems will be available from the manufacturer. The effect of combining two or more systems (d4) may require additional performance qualification (see ISO 17665-1:2006, Clause 8).

5 Product family (pf)

The product family assigned to a medical device should be based on attributes identified from the ones shown in 4.2. A number of product families that could be established from these attributes are listed in Table 6.

Use Table 6 to assign a product family to a medical device and then from this assignment identify the steam penetration resistance. For each medical device:

- select a level for each attribute a to d;
- establish a match to one of the product families in the table;
- note the product family and then from column 'e', the estimate for steam penetration resistance;
- if a match cannot be obtained, establish a new one and then by comparison with established product families and from performance qualification, estimate a steam penetration resistance.

A discussion and estimate for steam penetration resistance for three types of medical devices are shown in 5.1, 5.2 and 5.3. A user may need to establish additional product families for those designs that cannot be characterized into one of the seven designs illustrated in Table 2.

The steam penetration resistance assigned to each product family listed in Table 6 is estimated and judged from the attributes identified in Clause 4. This estimation is first based on the design of the medical devices in the family and then adjusted if influenced by the other attributes. A procedure set will often contain a range of medical devices and components each assigned a different product family and a different steam penetration resistance. The product family assigned to a procedure set should normally align with the medical device or component assigned the highest steam penetration resistance unless influenced by adjacent medical devices and/or components. Examples are illustrated in Annex B.

The actual steam penetration resistance will depend on the load configuration and any one of the following:

- design of the sterilizer;
- type of operating cycle;
- operational state of the sterilizer witnessed by validation and conformity to the requirements for scheduled periodic tests;
- quality of services delivered to the equipment witnessed by test;
- site.

5.1 Example 1 — pf 1

A shallow, thin wall, metal bowl.

- design: a1,
- material: b1,
- weight: c1,
- sterile barrier system and/or packaging system: d1.

Steam condensing on the bowl will cause a higher concentration of air on its surfaces. This air will be displaced by steam and sterilizing conditions will exist on its surface when the sterilization temperature is measured at the reference measurement point e.g. the chamber drain.

Nominal changes to the non-condensable gases (NCG) in the steam and/or to air leakage into the sterilizer chamber are unlikely to adversely affect the predicted efficiency of the sterilization process.

The estimated steam penetration resistance for this medical device is e1 (see Table 6) based on design a1. The other attributes of the device will not affect this estimation.

5.2 Example 2 — pf 24

A length of thin wall soft plastic tubing.

- design: a5,
- material: b2,
- weight: c1,