TECHNICAL ISO/TS

First edition
2013-04-15

Sterilization of health care products — Moist heat —

Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

Stérilisation des produits de santé — Chaleur humide —

Partie 3: Directives concernant la désignation d'un dispositif médical pour une famille de produits et catégorie de traitement pour la stérilisation à la vapeur

Reference number
ISO/TS 17665-3:2013(E)

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Published in Switzerland

Contents

Foreword

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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.