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Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

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National foreword

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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).

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

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The quality of water supplied to sterilizers and washer-disinfectors (WDs) used for processing medical devices is an important aspect of the effective functioning of that equipment and the ultimate safety and functioning of medical devices and other health care related equipment being processed.

Potable water can vary in its specific quality aspects within countries, between countries around the world and over time due to the supply source, means of transport or distribution, and storage. Although potable water is considered fit for consumption, it is not necessarily of sufficient quality for processing medical devices as its microbial and chemical quality can vary considerably. For this reason, it can be necessary for potable water to be subjected to some form(s) of treatment prior to use in sterilizers and WDs used for processing medical devices and other health care related products.

The quality of water is influenced by a number of variables that can be characterized as physical, chemical and microbiological attributes.

Water treatment systems can be configured in many ways. The primary goal of all water treatment systems is achieving the water quality specifications suitable for the products and each step of processing. Water can be treated by a variety of methods that yield different levels of water quality. Commonly used water treatments can include, for example, softening, deionization (DI), filtration, reverse osmosis (RO), ozonization, distillation and sterilization.

Country-specific guidance documents can recommend the quality of water to be used when processing medical devices or other health care products in sterilizers and WDs.

This document provides guidance on the quality of water for sterilizers, sterilization and WDs used to process health care products; specific water quality attributes are taken from the relevant sterilizer, sterilization or WD standards. The scope of this document specifically excludes making changes to the water quality attributes that are recommended in the source documents, but where discrepancies exist between different applications for water, for example between different sterilization modalities, these differences can be addressed in future revisions to those source documents.

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Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

1 Scope

1.1 Inclusions

This document provides guidance on the quality of water for sterilizers, sterilization and washer-disinfectors (WDs) used to process health care products.

This document covers the quality of water used directly for cleaning, thermal and chemical disinfection, rinsing and sterilization, as feedwater for the generation of steam, as a service to a sterilizer or WD, or as a cooling agent.

This document provides specific guidance on:

— water quality for different applications;

— water treatment systems;

— water distribution and storage;

— monitoring and control of water quality;

— investigating out of specification results.

NOTE Guidance given in this document can also be applied to specifications for the quality of water required for manual cleaning or disinfection of medical devices (see the ISO 17664 series).

1.2 Exclusions

This document does not supersede or modify requirements or test methods of published standards applying to:

— development, validation or routine control and monitoring of a sterilization process;

— sterilizers;

— WDs.

This document does not specify requirements for water treatment systems (see, for example, standards for particular sterilizers or WDs).

This document does not specify the water quality for manufacturing pharmaceuticals, cell-based health care products or medical devices.

This document does not provide guidance on the attributes of steam quality (see, for example, EN 285).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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