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Sterilization of health care products — Biological indicators —

Part 8: Method for validation of a reduced incubation time for a biological indicator

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 8: Méthode pour la validation d'un temps d'incubation réduit pour un indicateur biologique

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Foreword

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

A list of all parts in the ISO 11138 series can be found on the ISO website.

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.

Introduction

A biological indicator incubation time is the minimum period of cultivation required before making a final determination that a biological indicator is negative (shows no growth). The reference incubation time for biological indicators for established sterilization processes such as moist heat and ethylene oxide is 7 d (see ISO 11138-1:2017). In some instances where biological indicator results are needed as part of the product release process, a 7-day incubation time might not be practical. This is especially the case where biological indicators are used to monitor sterilization processes in hospitals or other health care facilities such as dental or general practitioner offices.

The purpose of a reduced incubation time procedure is to demonstrate recovery of the surviving test organisms within the specified reduced incubation time period. The reduced incubation time is a function of the test method and conditions used to establish the incubation time and is independent of the process parameters for the sterilization method used to deliver the lethality.

Biological indicators with an incubation time of less than 7 d (a Reduced Incubation Time, or RIT) have been in use since the 1970s. The methodology to determine the RIT was originally created by the biological indicator manufacturers. Later, the United States Food and Drug Administration published guidance for manufacturers seeking regulatory clearance to market biological indicators to health care facilities in the United States (see Reference [1]). This guidance contained a protocol for validating an incubation time that was less than 7 d. This document was specific to regulations for commercial practices in a single country and did not address requirements for RIT methodology outside of that application. The purpose of this document is to describe an internationally agreed approach to the validation of the reduced incubation time of a biological indicator.