



BSI Standards Publication

Aseptic processing of health care products

Part 2: Sterilizing filtration

National foreword

This British Standard is the UK implementation of EN ISO 13408-2:2018. It is identical to ISO 13408-2:2018. It supersedes BS EN ISO 13408-2:2011, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Date	Text affected
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English Version

Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)

Traitement aseptique des produits de santé - Partie
2: Filtration stérilisante (ISO 13408-2:2018)

Aseptische Herstellung von Produkten
für die Gesundheitsfürsorge - Teil 2:
Sterilfiltration (ISO 13408-2:2018)

This European Standard was approved by CEN on 2 January 2018.

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European foreword

This document (EN ISO 13408-2:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2018, and conflicting national standards shall be withdrawn at the latest by September 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13408-2:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, B, and C, which are an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annexes ZA, ZB or ZC, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 13408-1:2008 + Amd 1:2013	EN ISO 13408-1:2015	ISO 13408-1:2008 + Amd 1:2013
ISO 13408-5	EN ISO 13408-5:2011	ISO 13408-5:2006
ISO 11135	EN ISO 11135:2014	ISO 11135:2014
ISO 11137-1	EN ISO 11137-1:2015	ISO 11137-1:2006 + Amd 1:2013
ISO/DIS 11139:2017	prEN ISO 11139:2017	ISO/DIS 11139:2017
ISO 13485	EN ISO 13485:2016 + AC:2016	ISO 13485:2016
ISO 17665-1	EN ISO 17665-1:2006	ISO 17665-1:2006

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Endorsement notice

The text of ISO 13408-2:2018 has been approved by CEN as EN ISO 13408-2:2018 without any modification.

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Quality system elements	3
4.1 General	3
4.2 Management responsibility	3
4.3 Procurement of filters	3
5 Sterilizing filter characterization	3
5.1 General	3
5.2 Microbial removal effectiveness	4
5.3 Material effects	4
5.4 Environmental considerations	5
6 Process and equipment characterization	5
6.1 General	5
6.2 Risk management	5
6.3 Process characterization	6
6.4 Equipment characterization	6
7 Fluid definition	7
7.1 General	7
7.2 Microbiological quality	8
8 Process definition	8
8.1 General	8
8.2 Filter definition and characterization	9
8.2.1 General	9
8.2.2 Compatibility between the filter and fluid	9
8.2.3 Filter use	10
8.3 Filtration process definition	10
8.4 Integrity testing process definition	11
9 Validation	12
9.1 General	12
9.2 Validation of fluid-specific microbial retention by sterilizing filters for liquids	12
9.2.1 General	12
9.2.2 Test organism	13
9.3 Validation of the integrity test for sterilizing filters for liquids	14
9.4 Validation of filter interactions with the process fluid	15
9.5 Validation of the sterilization of filter system	15
9.6 Validation of fluid-specific microbial retention by sterilizing filters for gases	15
9.6.1 General	15
9.6.2 Aerosol retention	15
9.6.3 Validation of physical integrity testing	15
9.6.4 Compatibility and service life	16
9.6.5 Validation of the sterilization of the filter system for gases	16
10 Routine monitoring and control	16
11 Product release from sterilizing filtration	16
12 Maintaining process effectiveness	17
12.1 General	17
12.2 Recalibration	17

12.3	Maintenance of equipment.....	17
12.4	Requalification.....	17
12.5	Assessment of change.....	18
Annex A (informative) Guidance on the application of this document.....		19
Bibliography		34