
**Aseptic processing of health care
products —**

**Part 2:
Sterilizing filtration**

*Traitement aseptique des produits de santé —
Partie 2: Filtration stérilisante*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Published in Switzerland

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