



SLOVENSKI STANDARD

oSIST prEN ISO 19253:2026

01-marec-2026

Sterilizacija izdelkov za zdravstveno nego - Vlažna toplota - Zahteve za sterilizatorje, ki se uporabljajo za končno sterilizacijo vodnih tekočin v zaprtih posodah (ISO/DIS 19253:2026)

Sterilization of health care products - Moist heat - Requirements for sterilizers used for the terminal sterilization of aqueous liquid in sealed containers (ISO/DIS 19253:2026)

Sterilisation von Produkten für die Gesundheitsfürsorge - Anwendung von ISO/TS 22421 auf die Anforderungen an Sterilisatoren, die für die Endsterilisation von Produkten für die Gesundheitsfürsorge verwendet werden, die wässrige Flüssigkeiten in verschlossenen Behältern enthalten (ISO/DIS 19253:2026)

Document Preview

Stérilisation des produits de santé - Chaleur humide - Exigences relatives aux stérilisateurs utilisés pour la stérilisation terminale des liquides aqueux dans des récipients hermétiques (ISO/DIS 19253:2026)

<https://standards.iteh.ai/catalog/standards/sist/d089bd8d-17b0-4796-b9c2-05b117659500/osist-pren-iso-19253-2026>

Ta slovenski standard je istoveten z: prEN ISO 19253

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment
-----------	------------------------	-----------------------

oSIST prEN ISO 19253:2026

en,fr,de



DRAFT International Standard

ISO/DIS 19253

Sterilization of health care products — Moist heat — Requirements for sterilizers used for the terminal sterilization of aqueous liquid in sealed containers

ICS: 11.080.10

ISO/TC 198

Secretariat: **ANSI**

Voting begins on:
2026-01-30

Voting terminates on:
2026-04-24

iteh Standards
(<https://standards.iteh.ai>)
Document Preview

[oSIST prEN ISO 19253:2026](https://standards.iteh.ai/catalog/standards/sist/d089bd8d-17b0-4796-b9c2-05b117659500/osist-pren-iso-19253-2026)

<https://standards.iteh.ai/catalog/standards/sist/d089bd8d-17b0-4796-b9c2-05b117659500/osist-pren-iso-19253-2026>

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 19253:2026(en)

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2026

ISO/DIS 19253:2026(en)

iTeh Standards (<https://standards.iteh.ai>) Document Preview

[oSIST prEN ISO 19253:2026](https://standards.iteh.ai/catalog/standards/sist/d089bd8d-17b0-4796-b9c2-05b117659500/osist-pren-iso-19253-2026)

<https://standards.iteh.ai/catalog/standards/sist/d089bd8d-17b0-4796-b9c2-05b117659500/osist-pren-iso-19253-2026>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

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
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

ISO/DIS 19253:2026(en)

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions	3
4 General	7
4.1 Product definition	7
4.2 Equipment development	8
4.3 Calibration	8
5 Equipment design and construction	9
5.1 Safety and security	9
5.1.1 General	9
5.1.2 Over pressure protection devices (OPPD)	9
5.1.3 Over temperature protection devices	10
5.1.4 Door release safety system	10
5.1.5 Chamber empty protection system	11
5.2 Chamber	11
5.2.1 General	11
5.2.2 Dimensions	11
5.2.3 Design of water dispersion systems within the chamber	12
5.2.4 Doors	12
5.2.5 Chamber integrity	15
5.2.6 Pressure vessels	16
5.2.7 Uniformity of conditions	16
5.2.8 Ancillary equipment and components	17
5.3 Materials	19
5.4 Interlocks	20
5.5 Test connections	20
5.6 Vibration	21
5.7 User interfaces	21
6 Indicating, monitoring, controlling and recording	23
6.1 General	23
6.2 Automatic control	23
6.3 Control and monitoring system	24
6.4 Failure	26
6.4.1 General	26
6.4.2 Fault	27
6.4.3 Power failure	28
6.4.4 Other failures	28
6.5 Instrumentation	28
6.6 Indicating devices	32
6.7 Recorders	33
7 Service and local environment	34
7.1 General	34
7.2 Sterilizing agent and sterilant	35
7.3 Electrical supply	35
7.4 Water	35
7.5 Steam	36
7.6 Vacuum	37
7.7 Drains	37
7.8 Lighting	37
7.9 Compressed air	37

ISO/DIS 19253:2026(en)

7.10	Air and inert gases	38
7.11	Ventilation	38
8	Emissions	38
8.1	Electromagnetic emissions	38
8.2	Noise	38
8.3	Exhaust emissions	39
8.4	Heat emissions	39
9	Test instrumentation	40
10	Performance and assessment	40
10.1	General	40
10.2	Chamber integrity	40
10.3	Attainment of conditions - Thermometric	41
10.4	Microbiological performance	44
10.5	Pressure change	44
11	Information to be supplied	44
11.1	General	44
11.2	Information to be available prior to purchase	45
11.3	Post delivery information to be provided	46
11.4	Marking	47
11.5	Label	47
11.6	Instructions for use	47
11.7	Technical description	48
Annex A	(informative) Background to the development of ISO 19253	51
Annex B	(informative) Illustrations of the interrelationship between control and recording	53
Annex C	(normative) Methods for the determination of the dimensions of the sterilizer chamber and the usable chamber space	58
Annex D	(informative) Examples of contained product sterilization processes and an explanation of the stages and terminology associated with such processes	62
Annex E	(informative) Verification of the sterilizer's F_0 value accumulation system (if fitted)	67
Annex F	(normative) Test methods and reference loads for contained product sterilizers	71
Annex G	(informative) Suggestions for information which can be supplied by the purchaser of the sterilizer	86
Annex H	(normative) Test instrumentation	88
Annex I	(informative) Test methods for determining steam quality	94
Annex J	(informative) An exemplar thermometric approach to Performance Qualification when validating a contained product sterilization process according to ISO 17665:2024	96
Annex K	(informative) Potential hazards associated with the sterilization of aqueous fluids in sealed rigid containers	98
Annex L	(informative) Methods for locating heat penetration temperature sensors into aqueous liquids in sealed containers	100
Bibliography	109

ISO/DIS 19253:2026(en)

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 19253 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.