

**SLOVENSKI STANDARD**  
**oSIST prEN ISO 18969:2026**  
**01-februar-2026**

---

**Klinično ovrednotenje medicinskih pripomočkov (ISO/DIS 18969:2025)**

Clinical evaluation of medical devices (ISO/DIS 18969:2025)

Klinische Bewertung von Medizinprodukten (ISO/DIS 18969:2025)

Evaluation clinique des dispositifs médicaux (ISO/DIS 18969:2025)

Ta slovenski standard je istoveten z: <https://standards.iteh.ai>

Document Preview

---

**ICS:**

[oSIST prEN ISO 18969:2026](https://standards.iteh.ai/standard/oSIST_prEN ISO 18969:2026)

<https://standards.iteh.ai/standard/11.040.01> Medicinska oprema na splošno  
<https://standards.iteh.ai/standard/24084-0> Medical equipment in general

**oSIST prEN ISO 18969:2026**

**en,fr,de**





# DRAFT International Standard

## ISO/DIS 18969

### Clinical evaluation of medical devices

*Evaluation clinique des dispositifs médicaux*

ICS: 11.040.01

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

[oSIST prEN ISO 18969:2026](#)

<https://standards.iteh.ai/catalog/standards/sist/c5be4084-0d77-4827-9f56-63da5315c208/osist-pren-iso-18969-2026>

This document is circulated as received from the committee secretariat.

### ISO/CEN PARALLEL PROCESSING

ISO/TC 194

Secretariat: DIN

Voting begins on:  
**2025-12-15**

Voting terminates on:  
**2026-03-09**

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/DIS 18969:2025(en)

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

[oSIST prEN ISO 18969:2026](#)

<https://standards.iteh.ai/catalog/standards/sist/c5be4084-0d77-4827-9f56-63da5315c208/osist-pren-iso-18969-2026>



### COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

## ISO/DIS 18969:2025(en)

## Contents

Page

<b>Foreword</b>	<b>v</b>
<b>Introduction</b>	<b>vi</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Symbols and Abbreviations</b>	<b>5</b>
<b>5 General requirements</b>	<b>6</b>
5.1 Purpose of the clinical evaluation	6
5.2 Management Responsibilities	7
5.3 Clinical evaluation process	7
5.4 Clinical evaluation quality management	8
5.5 Competencies relevant for the clinical evaluation	9
5.6 Documentation of the clinical evaluation	9
<b>6 Clinical evaluation considerations throughout the life cycle</b>	<b>9</b>
6.1 Overall considerations	9
6.2 Planning considerations during design and development	10
<b>7 Clinical evaluation planning</b>	<b>11</b>
7.1 General	11
7.2 Identifying medical and non-medical alternatives	12
7.3 Identification of data sources for available knowledge	13
7.4 Identification of data sources for the device under evaluation	14
7.4.1 Non-clinical data relevant to the device under evaluation	14
7.4.2 Clinical data relevant to the device under evaluation	14
7.5 Special considerations	15
7.5.1 Transferability of clinical data	15
7.5.2 Medical devices with special clinical evaluation considerations	15
7.5.3 Considerations for the level of clinical evidence	15
<b>8 Clinical evaluation conduct and documenting</b>	<b>16</b>
8.1 Available knowledge	16
8.2 Device under evaluation	16
8.2.1 Data collection	16
8.2.2 Data appraisal	17
8.2.3 Data analysis and conclusions	17
<b>9 Overall assessment</b>	<b>18</b>
9.1 General considerations	18
9.2 Safety	18
9.3 Clinical performance or effectiveness, including clinical benefit(s)	18
9.4 Benefit-risk profile	19
9.5 Limitations	19
<b>10 Final conclusions</b>	<b>20</b>
<b>11 Additional activities</b>	<b>20</b>
<b>12 Update of the clinical evaluation</b>	<b>21</b>
<b>Annex A (informative) Clinical evaluation documentation: suggested outline</b>	<b>22</b>
<b>Annex B (informative) Methodology for data search - literature search</b>	<b>27</b>
<b>Annex C (informative) Appraisal of data</b>	<b>30</b>
<b>Annex D (informative) Analysis of data</b>	<b>32</b>
<b>Annex E (informative) Clinical evaluation activities during medical device life cycle stages</b>	<b>33</b>

## ISO/DIS 18969:2025(en)

Annex ZA (informative) Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered.....	35
Bibliography.....	42

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

[oSIST prEN ISO 18969:2026](#)

<https://standards.iteh.ai/catalog/standards/sist/c5be4084-0d77-4827-9f56-63da5315c208/osist-pren-iso-18969-2026>

## ISO/DIS 18969:2025(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](http://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](http://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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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](http://www.iso.org/members.html).

<https://standards.iteh.ai/catalog/standards/sist/c5be4084-0d77-4827-9f56-63da5315c208/osist-pren-iso-18969-2026>