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STN	**Neurochirurgické implantáty Sterilné hydrocefalické shunty na jednorazové použitie (ISO 7197: 2024)**	**STN EN ISO 7197** 85 2942

Neurosurgical implants - Sterile, single-use hydrocephalus shunts (ISO 7197:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/25

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EUROPEAN STANDARD
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EN ISO 7197

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ICS 11.040.40 Supersedes EN ISO 7197:2009

English Version

Neurosurgical implants - Sterile, single-use hydrocephalus shunts (ISO 7197:2024)

Implants neurochirurgicaux - Systèmes de dérivation stériles, non réutilisables, pour hydrocéphalie (ISO 7197:2024)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO 7197:2024)

This European Standard was approved by CEN on 28 July 2024.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (EN ISO 7197:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by May 2025, and conflicting national standards shall be withdrawn at the latest by May 2025.

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 ISO 7197:2009.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 7197:2024 has been approved by CEN as EN ISO 7197:2024 without any modification.

Annex ZA
(informative)

Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European Standard has been prepared under a Commission's standardization request "M/575" to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10.1 (f)	4.9, 4.11, 5.1.2	10.1 (f) is covered with respect to: dynamic breaking strength by 4.9. bursting pressure by 4.11. long term stability by 5.1.2 which specifies a test method and performance requirement for the valves.
10.1 (h)	4.2, 4.6	10.1 (h) is covered with respect to: radiopacity by 4.2. pressure-flow characteristics by 4.6.
10.2	7	10.2 is covered with respect to the material of the packaging being non-fibrous and lint-free by Clause 7.
11.1 (c)	4.4	11.1 (c) is covered with respected to resistance to leakage by 4.4.
14.2 (b)	4.10	14.2 (b) is covered with respect to magnetically induced forces, moments, and heating and with respect to image artefacts produced by the shunt under worst-case MR scanning conditions by 4.10.
23.1 (b)	6	23.1 (b) is covered with respect to marking indicating the intended direction of flow by Clause 6.
23.4 (e)	8.2 g), h), i), j) and k)	23.4 (e) is covered with respect to the flow characteristics of the valve by 8.2 g), h), i), j) and k).
23.4 (i)	8.2 a), b)	23.4 (i) is covered with respect to: instructions for assembly of the shunt system by 8.2 a). instructions for the pre and postoperative testing of the functionality of the shunt by 8.2 b).
23.4 (k)	8.2 b), c), e) and l)	23.4 (k) is covered with respect to: instructions for the pre and postoperative testing of the functionality of the shunt by 8.2 b) warning notices concerning the maximum

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		positive and negative pressure that can be applied to the system without impairing its performance by 8.2 c). an indication regarding how the flow direction of the device can be determined by 8.2 e). an instruction if and how the shunt shall be tested and/or readjusted after MR examination by 8.2 l).
23.4 (s)	8.3	23.4 (s) is covered with respect to warning against the hazards of exposure to magnetic fields by 8.3.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO/TR 14283	ISO/TR 14283:2018	Implants for surgery — Essential principles of safety and performance	-
ISO 14630:2024	ISO 14630:2024	Non-active surgical implants — General requirements	EN ISO 14630:2024

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 7197

Neurosurgical implants — Sterile, single-use hydrocephalus shunts

Implants neurochirurgicaux — Systèmes de dérivation stériles, non réutilisables, pour hydrocéphalie

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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 document 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 150, *Implants for surgery,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7197:2006) which has been technically revised.

The main changes are as follows:

— subclause 4.1 has been completely revised;

— terminology has been clarified and references have been updated.

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 shunt is defined as an artificial connection of two compartments inside the body. For the treatment of hydrocephalus, the ventriculo-atrial shunt has been introduced initially to control the intraventricular pressure in the brain of the patients. Today ventriculo-peritoneal shunts are preferably implanted. In special cases, a lumbo-peritoneal shunt is implanted. Normally, a hydrocephalus shunt includes a valve which determines the resulting intraventricular pressure in the brain of the patients and influences the flow rate through the shunt.

The following types of valve are currently commercially available.

a) Conventional differential-pressure valves (DP valves) are designed as ball-in-cone valves, membrane valves or silicone slit valves: They have one characteristic opening pressure. If the difference pressure between inlet and outlet exceeds this opening pressure the device opens. After opening, the different types of DP valve show a wide range of different flow characteristics. Differences due to a changed posture of the patient have no intended impact on the function of the devices.

b) Adjustable DP valves act like conventional DP valves: In contrast to non-adjustable devices, they introduce the possibility of a non-invasive readjustment of the opening characteristic after implantation. They do not take into account changes due to a changed posture of the patient.

c) Gravitation valves or hydrostatic devices that take into account the changed physics in a shunt due to a changed posture of the patient: These devices aim to avoid an unphysiological negative intraventricular pressure in the upright position of the patient, which can be the consequence of the hydrostatic pressure in shunts with adjustable or not adjustable DP valves. There are three different hydrostatic devices commercially available:

   — flow-reducing devices,

   — valves with a so-called “anti-siphon-device” or “siphon-control-device”, and

   — gravity-assisted devices.

d) Other adjustable valves, for example:

   — gravitation valves, which are adjustable hydrostatic devices present in addition to the characteristics of hydrostatic devices (group 4) with the possibility of a non-invasive readjustment of the opening performance of the device;

   — adjustable anti-siphon-device valves;

   — adjustable flow-reducing valves.

Due to the important technical differences, specific testing procedures are necessary to investigate the performance of the different valves.

The benefit of this document for the surgeon and the patient is to understand the information given by the manufacturer and to obtain standardized information about the performance of a well working product with new design characteristics. The benefit for the manufacturer is to specify the important requirements for shunts as a basis for investigations during development as well as for quality control during manufacture.

International Standard **ISO 7197:2024(en)**

Neurosurgical implants — Sterile, single-use hydrocephalus shunts

1 Scope

This document specifies the performance requirements for sterile, single-use non-active hydrocephalus shunts. This includes not only the valve, but also additional components such as tubes and reservoirs.

This document does not provide any recommendations on which type of valve is most suitable for any specific context of use.

This document specifies the mechanical and technical requirements to manufacture shunts and the technical information of the valve to be supplied by the manufacturer.

This document does not apply to active implants for the treatment of hydrocephalus.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 14283, *Implants for surgery — Essential principles of safety and performance*

ISO 14630:2024, *Non-active surgical implants — General requirements*