SLOVENSKI STANDARD
SIST EN ISO 20342-1:2022

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SIST EN ISO 20342-1:2019

Tehnični pripomočki za celovitost tkiv v ležečem položaju - 1. del: Splošne zahteve (ISO 20342-1:2022)

Assistive products for tissue integrity when lying down - Part 1: General requirements (ISO 20342-1:2022)

Hilfsmittel für die Gewebeintegrität im Liegen - Teil 1: Allgemeine Anforderungen (ISO 20342-1:2022)

Produits d'assistance pour l'intégrité des tissus en position allongée - Partie 1: Exigences générales (ISO 20342-1:2022)

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11.180.01	Pripomočki za onesposobljene in hendikepirane osebe na splošno	Aids for disabled and handicapped persons in general

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EUROPEAN STANDARD

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English Version

Assistive products for tissue integrity when lying down - Part 1: General requirements (ISO 20342-1:2022)

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This European Standard was approved by CEN on 26 June 2022.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 20342-1:2022) has been prepared by Technical Committee ISO/TC 173 "Assistive products" in collaboration with Technical Committee CEN/TC 293 “Assistive products and accessibility” the secretariat of which is held by SIS.

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of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.

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 20342-1:2019.

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 20342-1:2022 has been approved by CEN as EN ISO 20342-1:2022 without any modification.

INTERNATIONAL STANDARD

ISO 20342-1

Second edition
2022-07

Assistive products for tissue integrity when lying down —

Part 1: General requirements

Produits d'assistance pour l'intégrité des tissus en position allongée —
Partie 1: Exigences générales

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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 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).

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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 173, *Assistive products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 20342-1:2019), which has been technically revised.

The main changes are as follows:

— the Scope was clarified;

— Clause 2 was updated;

— Clause 3 was updated;

— subclause 7.3 about V-shaped openings was amended;

— subclause 7.7 and Table 4 were amended (regarding surface temperature);

— the bibliography was updated.

A list of all parts in the ISO 20342 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.

Introduction

This document addresses Assistive Products for Tissue Integrity (APTI). As some devices can be used/reused in more than one application environment, different requirements and test methods can apply to the same APTI, depending on the application environment.

APTI play a very important role in the prevention and treatment of pressure injuries. Another important role in the prevention and treatment of pressure injury is the clinical practice and the clinical evaluation. Guidance can be found in the NPUAP/EPUAP/PPPIA Guidelines[24].

Surfaces applied on operating theatre tables can also impact in the process of patient management and might need to be taken into consideration. It should be recognized however, patient stability and specialist equipment used during an operation often create conflicting priorities to those of an APTI.

Using this document, clinicians and manufacturers should consider the impact of other items (including additional APTI) used in conjunction with an APTI on tissue integrity and safety.

This document only covers general requirements to ensure safety of users.

Assistive products for tissue integrity when lying down —

Part 1: General requirements

1 Scope

This document specifies general requirements and related test methods that are relevant to assistive products for tissue integrity (APTI) in the lying position in different application environments such as hospitals, home care and institutions. This document applies to the safety of APTI that are intended to remain in situ during periods of lying, and to prevent and/or treat pressure injuries.

This document covers a range of different lying support surfaces intended to be used in combination with the appropriate support platform (adjustable included) or as a whole integrated system.

This document does not apply to medical beds.

This document also covers assistive products primarily intended for tissue integrity for changing a lying position and assistive products for maintaining a lying position.

This document does not apply to lying support surfaces used in combination with incubators or operating/surgical tables.

It also covers safety and performance test methods to ensure protection against injuries to the user.

This document addresses the combination of a full body support surface and an adjustable mattress support platform. It also covers safety and performance test methods to ensure protection against injuries to the user.

This document specifies requirements and test methods for APTI within the following classifications of ISO 9999:2022:

04 33 06 Assistive products for tissue integrity when lying down such as but not limited to

— mattresses and mattress overlays for pressure injury prevention, and

— mattress coverings for pressure injury prevention mattresses.

12 31 03 Assistive products for sliding and turning such as but not limited to the following:

Devices for changing position or direction of a person using sliding or turning techniques. The only products included are those intended to be used in a lying position and remain in situ as part of the lying support surface. They are the following:

— sliding products that glide one way and lock the other way;

— sheets and underlays in flexible materials with low friction;

— fabric sold by the metre, cut as required for repositioning use;

— powered turning product;

This excludes sliding boards unless the product is intended to be left in situ.

09 07 06 Positioning pillows, positioning cushions and positioning systems such as but not limited to

— leg positioners,