



SLOVENSKI STANDARD
SIST EN ISO 20342-1:2019/oprA1:2021
01-september-2021

Tehnični pripomočki za celovitost tkiv v ležečem položaju - 1. del: Splošne zahteve - Dopolnilo 1 (ISO 20342-1:2019/DAM 1:2021)

Assistive products for tissue integrity when lying down - Part 1: General requirements - Amendment 1 (ISO 20342-1:2019/DAM 1:2021)

Unterstützende Produkte zur Gewebeintegrität im Liegen - Teil 1: Allgemeine Festlegungen (ISO 20342-1:2019/DAM 1:2021)

Produits d'assistance pour l'intégrité des tissus en position allongée - Partie 1: Exigences générales - Amendement 1 (ISO 20342-1:2019/DAM 1:2021)

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Ta slovenski standard je istoveten z: EN ISO 20342-1:2019/prA1

ICS:

11.180.01	Pripomočki za onesposobljene in hendikepirane osebe na splošno	Aids for disabled and handicapped persons in general
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SIST EN ISO 20342-1:2019/oprA1:2021 en,fr,de

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DRAFT AMENDMENT

ISO 20342-1:2019/DAM 1

ISO/TC 173

Secretariat: SIS

Voting begins on:
2021-06-15Voting terminates on:
2021-09-07

Assistive products for tissue integrity when lying down —

Part 1: General requirements

AMENDMENT 1

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

ICS: 11.180.01

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ISO/CEN PARALLEL PROCESSING



Reference number
ISO 20342-1:2019/DAM 1:2021(E)

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This document was prepared by Technical Committee ISO/TC 173, *Assistive products for tissue integrity*.

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.

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Assistive products for tissue integrity when lying down —

Part 1: General requirements

AMENDMENT 1

Foreword

Add the following sentence after 7th paragraph:

A list of all parts in the ISO 20342 series can be found on the ISO website.

1 Scope

Replace 2nd paragraph with the following paragraphs:

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.

Replace 4th and 5th paragraphs by the following:

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.

2 Normative references

Add the following normative references to the list:

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 62366, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

Replace the term and definition in 3.9 by the following:

3.9

clinical investigation

systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a medical device

[SOURCE: ISO 14155:2020, 3.8, modified – Note 1 to entry was removed]