SLOVENSKI STANDARD
SIST EN ISO 14937:2001/AC:2004

01-februar-2004

Sterilizacija izdelkov za zdravstveno nego - Splošne zahteve za opredelitev lastnosti sterilizacijskih sredstev in za razvoj, validacijo ter rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO 14937:2000)

Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2000)

Sterilisation von Produkten für die Gesundheitsfürsorge - Allgemeine Anforderungen an die Charakterisierung eines Sterilisiermittels und an die Entwicklung, Validierung und Routineüberwachung eines Sterilisationsverfahrens für Medizinprodukte (ISO 14937:2000)

Stérilisation des produits de santé - Exigences générales pour la caractérisation d'un agent stérilisant et pour le développement, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux (ISO 14937:2000)

Ta slovenski standard je istoveten z: **EN ISO 14937:2000/AC:2003**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 14937:2001/AC:2004 **en**

INTERNATIONAL STANDARD ISO 14937:2000
TECHNICAL CORRIGENDUM 1

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RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 14937:2000 was prepared by Technical Committee ISO/TC 198.

Pages 18 and 19

Subclause D.2.5

Delete existing text of D.2.5 and replace it with the following text:

"D.2.5 If the inactivation of 10^6 microorganisms has been confirmed following D.2.4, determine the extent of treatment for the sterilization process by extrapolation to a predicted probability of a surviving microorganism of 10^{-6} or better, taking into account the nature of the inactivation kinetics effected by the sterilizing agent and the number and resistance of the microorganisms on the biological indicator.

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This approach is best suited to sterilizing agents that demonstrate linear inactivation kinetics. In such cases, the extent of treatment can be defined conservatively as twice that employed in D.2.4. For sterilizing agents that do not demonstrate linear inactivation kinetics, the nature of the inactivation kinetics should be investigated in order to derive a relationship from which it can be predicted that the specified probability of a microorganism surviving is not exceeded on applying the sterilization process.

NOTE A knowledge of the inactivation kinetics can be obtained as in 5.3.1 b); the nature of the inactivation kinetics may be influenced by the product."

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Annex ZA

Delete this entire annex.