



**SLOVENSKI STANDARD**  
**kSIST FprEN ISO 11137-2:2013**  
**01-april-2013**

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**Sterilizacija izdelkov za zdravstveno nego - Sevanje - 2. del: Določanje odmerka sterilizacije (ISO/FDIS 11137-2:2013)**

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO/FDIS 11137-2:2013)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 2: Festlegung der Sterilisationsdosis (ISO/FDIS 11137-2:2013)

Stérilisation des produits de santé - Irradiation - Partie 2: Établissement de la dose stérilisante (ISO/FDIS 11137-2:2013)

**Ta slovenski standard je istoveten z: FprEN ISO 11137-2**

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**ICS:**

11.080.01 Sterilizacija in dezinfekcija na splošno Sterilization and disinfection in general

**kSIST FprEN ISO 11137-2:2013 en**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**FprEN ISO 11137-2**

January 2013

ICS 11.080.01

Will supersede EN ISO 11137-2:2012

English Version

## Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO/FDIS 11137-2:2013)

Stérilisation des produits de santé - Irradiation - Partie 2:  
Établissement de la dose stérilisante (ISO/FDIS 11137-  
2:2013)

Sterilisation von Produkten für die Gesundheitsfürsorge -  
Strahlen - Teil 2: Festlegung der Sterilisationsdosis  
(ISO/FDIS 11137-2:2013)

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

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## Contents

	Page
Foreword.....	3

## Foreword

This document (FprEN ISO 11137-2:2013) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 11137-2:2012.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

### Endorsement notice

The text of ISO/FDIS 11137-2:2013 has been approved by CEN as FprEN ISO 11137-2:2013 without any modification.



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## Sterilization of health care products — Radiation —

### Part 2: Establishing the sterilization dose

*Stérilisation des produits de santé — Irradiation —  
Partie 2: Établissement de la dose stérilisante*

Please see the administrative notes on page iii

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