INTERNATIONAL STANDARD

ISO 11137-1

First edition 2006-04-15 **AMENDMENT 2** 2018-11

Sterilization of health care products — Radiation —

Part 1:

iTeh S7

Requirements for development, validation and routine control of a sterilization process for medical

(standards.iteh.ai)

AMENDMENT 2: Revision to 4.3.4 and

ISO 11787-1:2006/Amd 2:2018

https://standards.iteh.avcatalog/standards/sist/f5ba65a4-d3e9-4c4d-ba3f-

f6480c527306/iso-11137-1-2006-amd-2-2018

Stérilisation des produits de santé — Irradiation —

Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux

AMENDEMENT 2: Révision de 4.3.4 et de 11.2



iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 11137-1:2006/Amd 2:2018 https://standards.iteh.ai/catalog/standards/sist/f5ba65a4-d3e9-4c4d-ba3f-f6480c527306/iso-11137-1-2006-amd-2-2018



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A list of all parts in the ISO 114137 series can be found to 1 the ISO website a 3ff6480c527306/iso-11137-1-2006-amd-2-2018

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Sterilization of health care products — Radiation —

Part 1:

Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 2: Revision to 4.3.4 and 11.2

4.3.4

Add the following sentence to the end of the clause:

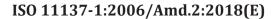
Detailed guidance on dosimetry and associated measurement uncertainty is given in ISO 11137-3.

11.2

Replace the second sentence with the following: PREVIEW

The procedure(s) shall define the requirements (see 9.4.3 or 9.4.4 as appropriate) for designating a sterilization process as conforming.

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