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AMENDMENT 1
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Sterilization of health care products — Radiation —

Part 2: Establishing the sterilization dose

AMENDMENT 1

Stérilisation des produits de santé — Irradiation —
Partie 2: Établissement de la dose stérilisante
AMENDEMENT 1

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 204, *Sterilization of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Sterilization of health care products — Radiation —

Part 2:
Establishing the sterilization dose

AMENDMENT 1

Clause 2 Normative references

Add the following new normative references:

ISO 11137-1:2006/Amd1:2013, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1*

ISO 11137-1:2006/Amd2:2018, *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*

ISO 13004: 20—[1], *Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method* VD_{max}^{SD}

6.4

Add the following new subclause:

6.4 If a sterilization dose of 17,5 kGy, 20 kGy, 22,5 kGy, 27,5 kGy, 30 kGy, 32,5 kGy or 35 kGy is established, it shall be substantiated by one of the following methods:

a) Method VD_{max}^{SD} of ISO 13004:20—;

b) Method 1 (see Clause 7), subject to the derived sterilization dose taking a value less than or equal to the selected sterilization dose and achieving maximally an SAL of 10^{-6};

c) Method 2 (see Clause 8), subject to the derived sterilization dose taking a value less than or equal to the selected sterilization dose and achieving an SAL of 10^{-6}; or

d) a method providing equivalent assurance to that of a), b) or c) above in achieving maximally an SAL of 10^{-6}.

Clause 9

Replace clause title with the following:

9 Method VD_{max} — Substantiation of a selected sterilization dose

9.1

Replace subclause title, add new first paragraph and replace original first paragraph as follows:

1) Under preparation. Stage at the time of publication: ISO/DIS 13004.

9.1 Selected doses and rationale

Rationale and methods for substantiation of sterilization doses of 15 kGy and 25 kGy using Method VD_{max} are provided in Clause 9. Rationale and methods for substantiation of sterilization doses of 17,5 kGy, 20 kGy, 22,5 kGy, 27,5 kGy, 30 kGy, 32,5 kGy or 35 kGy using Method VD_{max} are provided in ISO 13004:20—.

Operationally, Method VD_{max} for substantiation for a selected sterilization dose is similar to dose setting by Method 1 (see Clause 7); it also requires a determination of bioburden and the performance of a verification dose experiment.