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AMENDMENT 1
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Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1

Stérilisation des produits de santé — Formaldéhyde et vapeur à faible température — Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation pour dispositifs médicaux

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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AMENDMENT 1

Page 2, Clause 3 Terms and definitions

Delete all cross-references within the definitions to other terms defined in Clause 3.

3.18

Replace the sentence after the list ("and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means") with the following:

"and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means".

3.18

Correct SOURCE statement

from:

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]

to:

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added and the paragraph after the first list has been modified to include "in or on the human body".]

3.41

Replace term and definition with the correct definition from ISO 11139:2018, 3.137 as follows:

3.41
inactivation curve
graphical representation of decrease in viability of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions

11.1 b) and c)

Replace 11.1 b) and c) with the following text:

b) if chemical indicators are used as part of the product release, the complete colour change of these (see 8.4 and 10.3);

c) if biological indicators or PCDs containing BIs are used as part of the product release, acceptable results after cultivation of these (see 8.3 and 10.2); and

Table D.1

Replace wrong cross-reference in line "3 emission to air"/column "Use, Stage C", second to last line from C.9.3.4 to C.9.4.4.

Environmental aspects (inputs and outputs)	Product life-cycle			
	Production and reproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
	Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
3 Emission to air	Introduction 5.1 5.5 6.3.3 8.6 9.3.1 9.3.3 9.4.2.2 C.9.3.4 C.9.4.4	—	Introduction 5.1 5.5 6.3.3 8.6 9.3.1 9.3.3 9.4.2.2 C.9.3.4 C.9.4.4	—