



15 April 2020

(20-2932)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>THE STATE OF KUWAIT</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Public Authority for Industry (PAI) Kuwait Standard & Metrology Department (KUWSMD) Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Public Authority for Industry (PAI) P.O.Box:4690 Safat 13047 Kuwait Code: 65451 Kuwait Tel.:(+965) 25302630 Fax +965) 25302625 E-mail: Enquiry_point@pai.gov.kw Website: http://www.pai.gov.kw
3. Notified under Article 2.9.2 [], 2.10.1 [X], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): All products fall under scope of ISO 11737-1:2018 "Sterilization of health care products — Microbiological methods —Part 1: Determination of a population of microorganisms on products (ICS 11.080.01; 07.100.10); Sterilization and disinfection in general (ICS 11.080.01)
5. Title, number of pages and language(s) of the notified document: Sterilization of health care products — Microbiological methods —Part 1: Determination of a population of microorganisms on products) (48 page(s), in English)
6. Description of content: Specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package. NOTE 1 The nature and extent of microbial characterization is dependent on the intended use of bioburden data. NOTE 2 See <u>Annex A</u> for guidance on Clauses 1 to 9. This document does not apply to the enumeration or identification of viral, prion or protozoan contaminants. This includes the removal and detection of the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

	<p>NOTE 3 Guidance on inactivating viruses and prions can be found in ISO 22442-3, ICH Q5A(R1) and ISO 13022.</p> <p>This document does not apply to the microbiological monitoring of the environment in which health care products are manufactured.</p>
7.	<p>Objective and rationale, including the nature of urgent problems where applicable: Environment and consumer protection; Consumer information, labelling; Protection of human health or safety; Protection of the environment</p>
8.	<p>Relevant documents:</p> <p>NA. This document is provided by ISO Standards.</p>
9.	<p>Proposed date of adoption: 60 days from date of publication but it will be implemented in one day after approved by Kuwait ministry of commerce and industry due to corona virus (COVID-19) situation.</p> <p>Proposed date of entry into force: 180 days but due to urgent situation of corona virus (COVID-19) it will be implemented in 7 days from date of publication of approved version by Kuwait ministry of commerce and industry, in line with health precautions related to dealing and limiting the spread of corona virus (COVID-19).</p>
10.	<p>Final date for comments: 60 days from notification</p>
11.	<p>Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>ISO. This document was adopted by State of Kuwait under membership in International Standards Organization (ISO).</p> <p>Public Authority for Industry (PAI) P.O.Box:4690 Safat 13047 Kuwait Code: 65451 Kuwait Tel.:(+965) 25302630 Fax +965) 25302625 E-mail: Enquiry_point@pai.gov.kw Website: http://www.pai.gov.kw</p>