



21 February 2018

(18-1126)

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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>EGYPT</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Egyptian Organization for Standardization and Quality 16 Tadreeb El-Modarrebeen St., Ameriya, Cairo – Egypt E-mail: eos@idsc.net.eg / eos.tbt@eos.org.eg Website: http://www.eos.org.eg Tel.: + (202) 22845528 Fax: + (202) 22845504 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:
3. Notified under Article 2.9.2 [X], 2.10.1 [], 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): ICS 11.080.10 Sterilizing equipment
5. Title, number of pages and language(s) of the notified document: Ministerial Decree No. 1307/2017 (2 pages, in Arabic) mandating the Egyptian Standard ES 8138/2017 "Sterilization - Steam sterilizers - Large sterilizers" (106 pages, in English).
6. Description of content: The Ministerial Decree No. 1307/2017 gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 8138/2017 which specifies the essential requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of medical devices and their accessories contained in one or more sterilization modules. The test loads described in this standard are selected to represent the majority of loads (i.e. wrapped goods consisting of metal, rubber and porous materials) for the evaluation of general purpose steam sterilizers for medical devices. However, specific loads (e.g. heavy metal objects or long and/or narrow lumen) will require the use of other test loads. This Standard applies to steam sterilizers designed to accommodate at least one sterilization module or having a chamber volume of at least 60 l. Worth mentioning is that this standard technically adopts EN 285:2015
7. Objective and rationale, including the nature of urgent problems where applicable: Health and consumer protection

8. Relevant documents: <ul style="list-style-type: none">• Ministerial Decree No. 1307/2017• EN 285:2015
9. Proposed date of adoption: 15 October 2017 Proposed date of entry into force: 24 November 2017
10. Final date for comments: 60 days from notification
11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: Egyptian Organization for Standardization and Quality Address: 16 Tadreeb El-Modarrebeen St., Ameriya, Cairo- Egypt E-mail: eos@idsc.net.eg / eos.tbt@eos.org.eg Website: http://www.eos.org.eg Tel: + (202) 22845528 Fax: + (202) 22845504