



12 August 2016

(16-4350)

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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 Address: 16 Tadreeb El-Modarrebeen St., Ameriya, Cairo – Egypt Tel.: + (202) 22845528/22845522/228455 24 Fax: + (202) 22845504 E-mail: eos@idsc.net.eg / tbteos@eos.org.eg Website: http://www.eos.org.eg 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): Hospital equipment (ICS: 11.140)
5. Title, number of pages and language(s) of the notified document: Ministerial Decree No. 243/2016 (2 pages, in Arabic) mandating the Egyptian Standard ES 7411/2016 "Surgical Drapes, Gowns and Clean Air Suits, Used as Medical Devices for Patients, Clinical Staff and Equipment- General Requirements for Manufacturers, Processors and Products, Test Methods, Performance Requirements and Performance Levels" (21 pages, in Arabic)
6. Description of content: The Ministerial decree mandates that the producers and importers must abide by ES 7411/2016. Producers and importers are given a transitional period of six months. This standard applies to surgical coverings, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment. Worth mentioning is that this standard complies with EN13795:2011+A1:2013.
7. Objective and rationale, including the nature of urgent problems where applicable: Human health and safety requirements
8. Relevant documents: <ul style="list-style-type: none">Ministerial decree No. 243/2016EN13795:2011+A1:2013
9. Proposed date of adoption: 19 March 2016 Proposed date of entry into force: 21 April 2016

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| 10. Final date for comments: 60 days from the date of the 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
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