



10 January 2018

(18-0252)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>EGYPT</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Egyptian Organization for Standardization and Quality 16 Tadreeb El-Modarrebeen St., Ameriya, Cairo – Egypt E-mail: <a href="mailto:eos@idsc.net.eg">eos@idsc.net.eg</a> / <a href="mailto:tbteos@eos.org.eg">tbteos@eos.org.eg</a> Website: <a href="http://www.eos.org.eg">http://www.eos.org.eg</a> Tel.: + (202) 22845528 Fax: + (202) 22845504  <b>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:</b>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> ICS 11.040.20 (Transfusion, infusion and injection equipment)
<b>5. Title, number of pages and language(s) of the notified document:</b> Ministerial Decree no 1002/2017 (3 pages, in Arabic), mandating the Egyptian standard: <ul style="list-style-type: none"><li>• The Egyptian Standard ES 5526-3/2017 for Transfusion equipment for medical use - Part 3: Blood-taking sets for single use (18 pages, in English).</li><li>• The Egyptian Standard ES 5526-4/2017 for Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed (22 pages, in English).</li></ul>
<b>6. Description of content:</b> The Ministerial Decree No.1002/2017 gives the producers and importers a transitional period of 6 months to abide by the Egyptian standard ES 5526-3/2017, ES 5526-4/2017 This standards specifies: <ul style="list-style-type: none"><li>• Requirements for types of blood-taking sets for medical use in order to ensure functional inter changeability of transfusion equipment. It is applicable to sterilized blood-taking sets intended for single use only.</li><li>• Requirements for single use transfusion gravity sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.</li></ul> <p>Worth mentioning is that those standards comply with ISO 1135-3:2016 and ISO 1135-4:2015</p>
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Safety requirements

<b>8. Relevant documents:</b>
<ul style="list-style-type: none"><li>• The Ministerial Decree No.1002/2017</li><li>• ISO 1135-3:2016</li><li>• ISO 1135-4:2015</li></ul>
<b>9. Proposed date of adoption:</b> 13 July 2017 <b>Proposed date of entry into force:</b> 2 August 2017
<b>10. Final date for comments:</b> 60 days from notification
<b>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  Egyptian Organization for Standardization and Quality Address: 16 Tadreeb El-Modarrebeen St., Ameriya, Cairo- Egypt Tel: + (202) 22845528 Fax: + (202) 22845504 E-mail: <a href="mailto:eos@idsc.net.eg">eos@idsc.net.eg</a> / <a href="mailto:tbteos@eos.org.eg">tbteos@eos.org.eg</a> Website: <a href="http://www.eos.org.eg">http://www.eos.org.eg</a>