



8 January 2020

(20-0102)

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Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

### *Addendum*

The following communication, dated 7 January 2020, is being circulated at the request of the delegation of Egypt.

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Products covered: Quality management and quality assurance (ICS 03.120.10), Laboratory medicine in general (ICS 11.100.01)

This addendum concerns the notification of the Ministerial Decree No.1094/2019 (1 page, in Arabic) that gives the producers and importers twelve-month transitional period to abide by the Egyptian Standard ES 8281 "Medical analysis laboratories – minimum requirements for design, administrative and technical requirements for construction and operation" (19 pages, in Arabic).

It should be noted that the draft of this Egyptian standard was formerly notified in G/TBT/N/EGY/220 dated 17 September 2019.

Worth mentioning is that this standard complies with:

- ISO 15189:2012.
- Laboratory quality management system: handbook - 1. Laboratories — organization and administration, 2. Laboratories — handbooks, 3. Laboratories techniques and procedures — standards, 4. Quality control, 5. Manual - WHO document No. (ISBN 978 92 4 154827 4) Version 1.1.

Producers and importers are kept informed of any amendments in the Egyptian standard through the publication of administrative orders in the official gazette.

Proposed date of adoption: 29/11/2019

Proposed date of entry into force: 17/12/2019

Agency or authority designated to handle comments and text available from:

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