Temporary Guidance

Corona Virus (Covid-19) IVD Tests - Emergency Use Authorization (EUA)

Medical Devices Sector

Issue number: 2.0

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This guidance document will be immediately implemented without prior public comment, SFDA will still review all comments received and revise the guidance document as appropriate.

Content

Purpose

The purpose of this guidance is to clarify the requirements of Corona Virus (Covid-19) IVD Tests Emergency Use Authorization (EUA) along with providing the minimum medical device quality and safety requirements in order to accelerate its entry into the Kingdome of Saudi Arabia –KSA.

Under the condition of completing the procedures for registration and scientific evaluation of the technical documents of the specified medical device in according to " Guidance on Requirements for Medical Device Marketing Authorization - MDS-G5" within 60 days from the Emergency Use Authorization issuance date.

Scope

This guide applies to medical devices and In-vitro medical devices:

- Manufacturers
- Importers
- Authorized Representatives

Requirements

<u>During the Corona crisis (COVED-19)</u> Disclaimer: SFDA disclaim liability in the event of technical defects or adverse events resulting after placing in KSA market. Responsibility lies with the applicant/ manufacturer.	- The medical device/product is licensed from other regulatory authorities (if possible). - The manufacturer shall have Quality Management System (ISO 13485:2016). - Authorized reprehensive for external manufacturer. - The establishment (importer/ applicant) shall have valid license issued by SFDA. - Submit a written acknowledgment to complete the procedures of registration and scientific evaluation for medical device within 60 days from date of emergency use authorization issuance.
<u>Technical file requirements</u> Shall be available within 60 days from date of emergency use authorization issuance. (to complete the procedures of SFAD registration and scientific evaluation for technical documents)	- Devices and Accessories Information - Design and Manufacturing Information - Manufacturer Quality Management System (ISO 13485:2016) - Essential Principles , Conformance Evidence - Benefit-risk Analysis and Risk Management - Applicable Standards/National Regulations e.g. Sterilization and Bacteria & Viruses Protection Standards - Product Verification and Validation (including clinical evaluation and biocompatibility) - Vigilance and Post Market Surveillance

Note:

Due to the current circumstances, these requirements are subject to regular review and maybe amend by the SFDA when needed.

Relevant Guidelines

- **MDS – IR6:** Implementing Rule on Marketing Authorization
- **MDS-G5:** Guidance on Requirements for Medical Device Marketing Authorization
- **MDS – G44:** SFDA Recognized Standards

For further information

For further information, please contact us through:

- Regulation and standard section (md.standards@sfda.gov.sa)

- Product registration support section (md.rs@sfda.gov.sa)