الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector

SFDA Updates

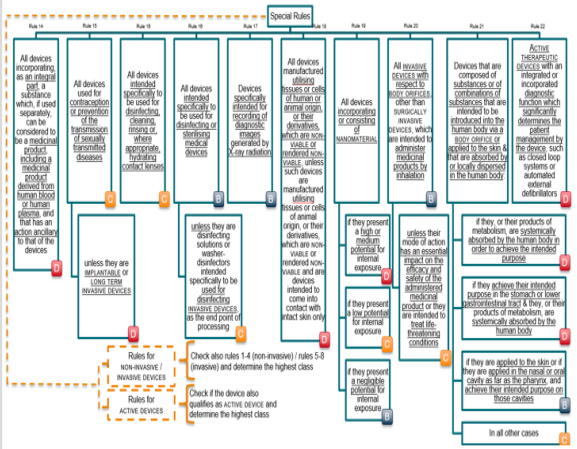
December 2020

Most Recent Regulatory Updates

1- SFDA Risk Based Classification

SFDA Has published Guidance (MDS – G42) for classification Rules in accordance to IMDRF and AHWP/GHWP Risk based Classes (A,B,C,and D)

MD Classification levels	IVD Classification levels
Class A	Class A
Class A – supplied sterile	
Class A – incorporating a measuring function	
Class A – reusable surgical instruments	
Class B	Class B
Class C	Class C
Class D	Class D



4.2.3.2 General explanation of rules, practical issues and examples

4.2.3.2.1 Rule 1

This is a fallback rule applying to all devices that are not covered by a more specific rule.

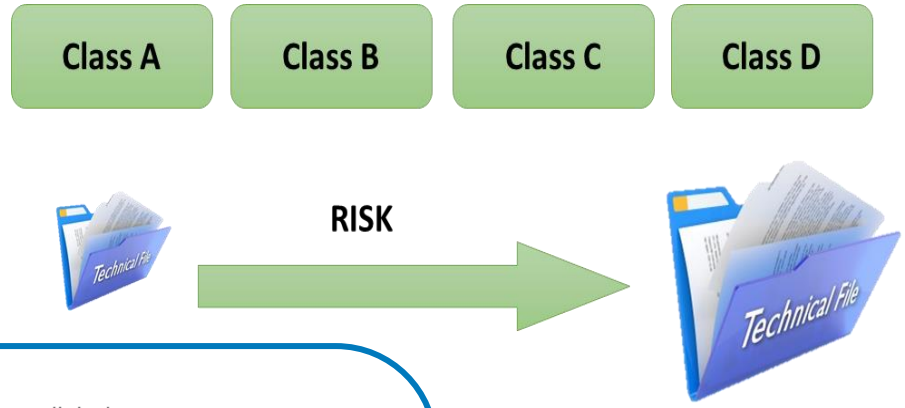
This is a rule that applies in general to devices that come into contact only with intact skin or that do not touch the patient.

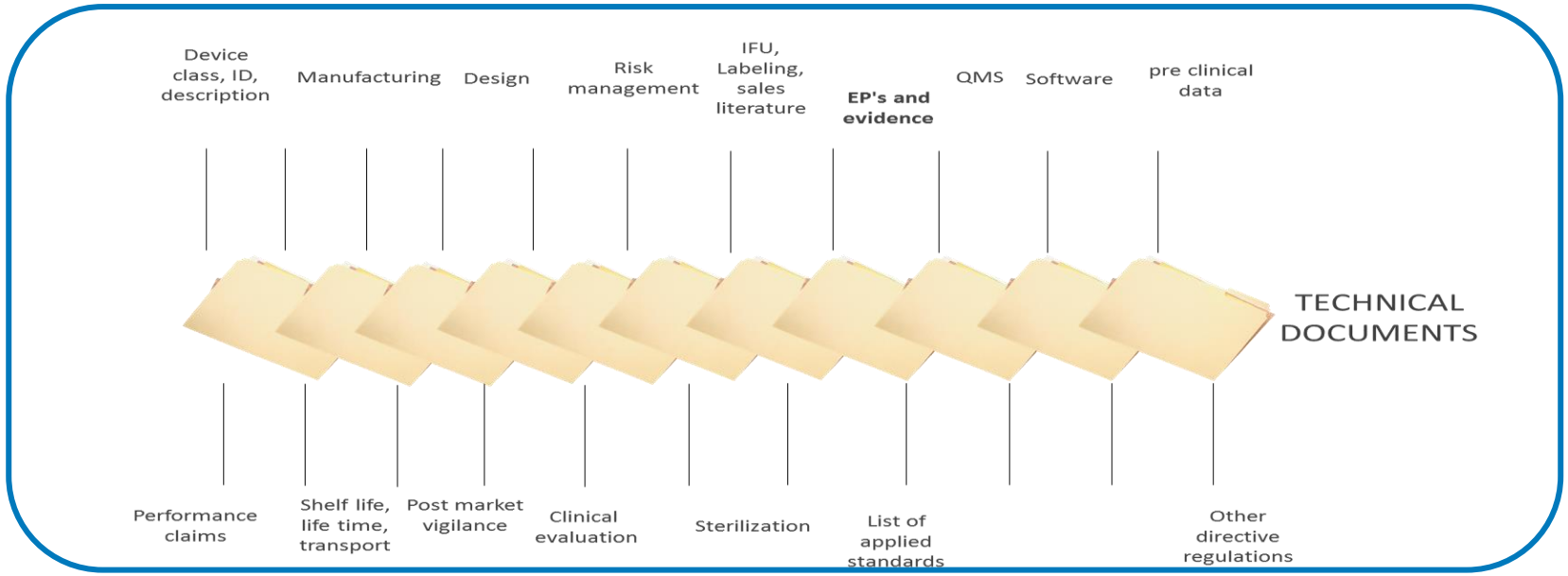
Some non-invasive devices are indirectly in contact with the body and can influence internal physiological processes by storing, channeling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body. These must be excluded from the application of this Rule and be handled by another rule because of the hazards inherent in such indirect influence on the body.

RULE 1	Description & examples
All non-invasive devices are classified as class A, unless one of the rules set out hereinafter applies.	• Body liquid collection devices intended to be used in such a way that a return flow is unlikely (e.g. to collect body wastes such as urine collection bottles, ostomy pouches, incontinence pads or collectors used with wound drainage devices). They may be connected to the patient by means of

2- Medical Device Technical File Assessment

- Manufacturers of Medical Devices Shall submit the **Technical File** To SFDA.
- Approvals from Other Authorities are considered as **supporting documents**.
- **Technical File Contents** are specified clearly in SFDA Guidance (G5)





3- Quality Management System (ISO13485)

- Local and Overseas Manufacturers of Medical Devices Shall establish a Quality Management system.
- SFDA Has adopted the latest version of ISO13485:2016.
- The Saudi standard is : (SFDA/GSO.ISO 13485:2017)

4- Medical Devices Clinical (Trial) Investigations

- **Performance Evaluation** Studies of In Vitro Diagnostics Medical Devices (PESIVD) and
- **Clinical Investigations (Trials)** of Medical Devices within KSA Shall be approved by SFDA before commencement and comply with ISO 14155:2020

[redacted]

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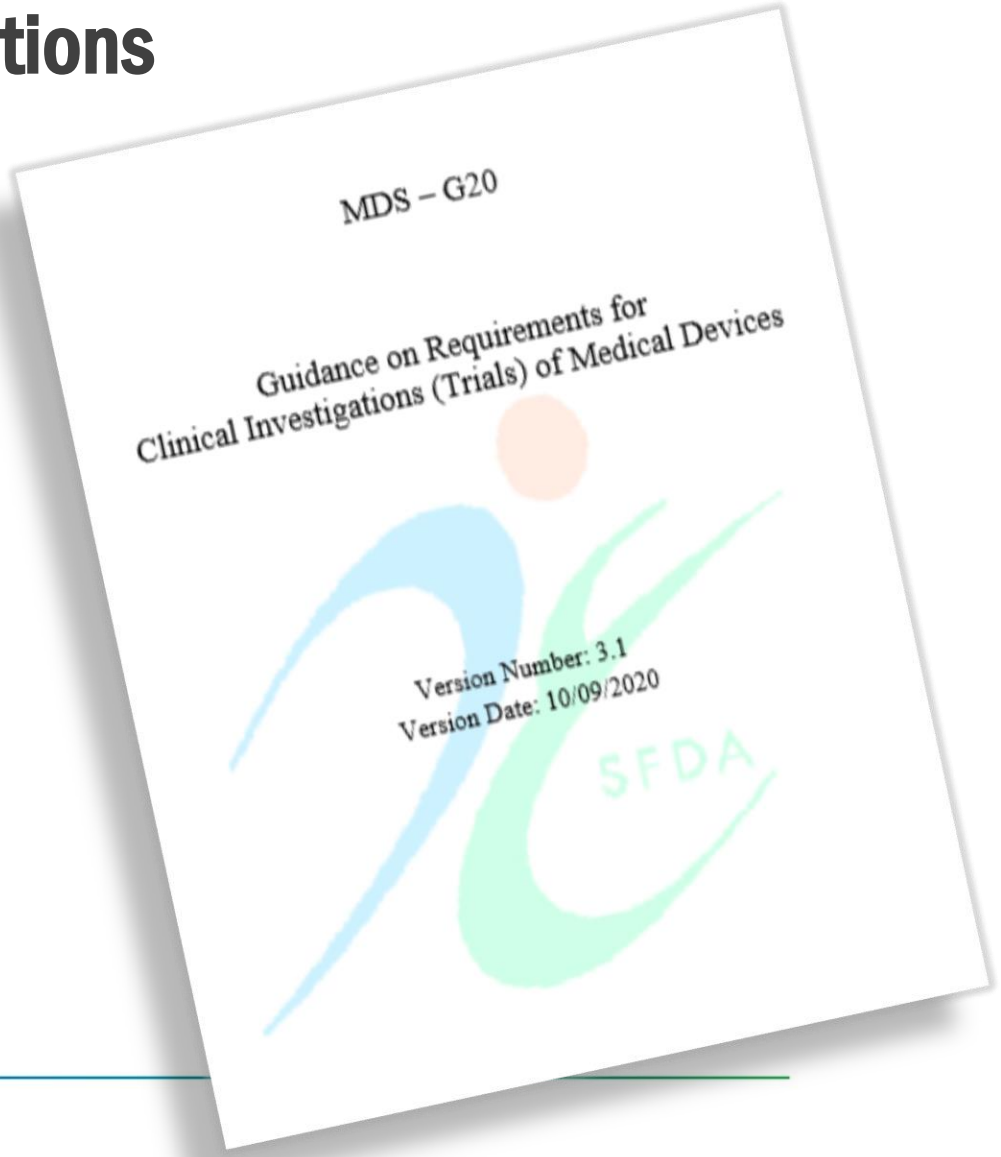
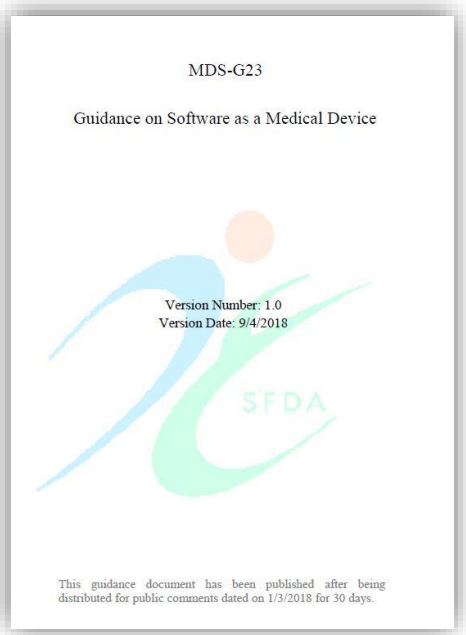
ISO 14155:2020



5- SFDA New Guidelines covering advanced technology and applications

- ✓ New Guidelines covering advanced technology and applications:
  - ✓ Medical devices **Cybersecurity** (two guidance documents one created for healthcare providers and one for manufacturers).
  - ✓ **Software** as a Medical Device
  - ✓ **3D printing** in medical devices
  - ✓ **Innovative** Medical Devices
  - ✓ **E-IFU** Requirements
  - ✓ **Artificial intelligence** (AI) (draft)


MDS-G23

Guidance on Software as a Medical Device

Version Number: 1.0
Version Date: 9/4/2018

This guidance document has been published after being distributed for public comments dated on 1/3/2018 for 30 days.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MDS – (DRAFT) G xx

Guidance on Regulatory Considerations for Artificial Intelligent/Machine learning software as Medical Device (SaMD)

Version Number: 0.0
Version Date: xx/xx/2020

6- SFDA- Unique Device Identification UDI

- ✓ The manufacturer, or its authorized representative, shall submit and maintain the appropriate data to UDI database
- ✓ Shall be **checked and maintained** periodically be manufacturer
- ✓ The data for new UDI-DI shall be available in UDI database at the time the device is placed on the market.
- ✓ Ensure all data in GHAD System & Saudi-DI are accurate and valid such as models name, GMDN code , …)

Go to https://udi.sfda.gov.sa/

7- SFDA monitors facilities with radiation-emitting devices to ensure proper compliance

Safe use of medical devices

SFDA Medical Devices Radiological Health Department	
Radiological Health Role	**Impact of Devices and SFDA Role**
Radiological Health function	
Publish National Diagnostic Reference Level for radiation dosing	**High risk/ wide-spread impact:** Radiological products are used on many patients over the device lifespan and can impact millions of patients
Publish best practices for safe use of medical devices covering healthcare providers and cosmetic clinics	**Device performance over time:** Performance of radiological devices will evolve with use necessitating continuous maintenance and calibration
	Low level of external support: There is a capability gap in other agencies to adequately assess and monitor radiological facilities within the Kingdom
Monitor radiological products and their operating environments	**SFDA monitoring:** SFDA monitors facilities that use radiation-emitting devices within the Kingdom, including: • Hospitals • Dental clinics • Polyclinics • Cosmetic clinics
	External support: SFDA has option to outsource activities to consultation offices and CABs. SFDA is also working with CBAHI & MoH so they adopt requirements

8- SFDA medical devices efforts during COVID-19 pandemic

- ✓Creating SFDA special evaluation for Corona Virus (Covid-19) IVD Tests - Emergency Use Authorization (EUA)
- ✓Acceleration of approval to obtain marketing authorization of any devices needed during pandemic
- ✓Develop guidance documents for:
  - ✓Protective **Medical Goggles and Face Shields** – Recognized Standards
  - ✓ General Requirements for Medical Devices Manufacturing
  - ✓ Requirements for **Ventilators,** Ventilator Tubing Connectors, and Ventilator Accessories – Recognized Standards Requirements for **Medical Masks and Particulate Respirators** – Recognized Standard

- To access these guidelines and more visit the Saudi FDA website via the below link

https://www.sfda.gov.sa/en/regulations?tags=3

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as we are always happy to assist..

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Please contact the International Cooperation Department (Governance) on

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THANK YOU