Saudi Food & Drug Authority (SFDA)

The Saudi Food & Drug Authority is the medical device regulatory authority in Saudi Arabia. As the name implies, it is responsible for regulating food and drugs, as well as medical devices. The SFDA is also responsible for regulating in vitro diagnostics (IVDs), prescription eye glasses, and contact lenses/solutions.

Within the SFDA, the Medical Devices Sector is specifically responsible for overseeing medical device and IVD regulations.

Legal Framework Governing Medical Devices

The SFDA was empowered to regulate medical devices by **Royal Decree No (6/M) on 25/1/1428H** (13 February 2007), and by Council of Ministers Decree No 181 on 03/06/1428H (18 June 2007).

The regulatory system was implemented through the **Medical Devices Interim Regulations of 27 December 2008**.

The SFDA will use this system until final legislative regulations are enacted. The Medical Devices Interim Regulations are complemented by the **Implementing Rules (MDS-IR 1–8)**, which include the following:

• IR1 - Designation and Oversight of Conformity Assessment Bodies
• IR2 - Establishment Registration
• IR3 - Medical Devices Listing
• IR4 - Establishment Licensing
• IR5 - Licensing of Authorized Representatives
• IR6 - Marketing Authorization
• IR7 - Post-Marketing Surveillance
• IR8 - Safeguard Procedures

Product grouping

Official fees for device registration in the KSA are relatively high, ranging from roughly $4,000 to $6,000 USD as of January 2017. Therefore, proper grouping of products into systems or product families is an important strategy to minimize the number of individual registrations you need.

The **Guidance on Medical Devices Bundling/Grouping Criteria** (MDS-G7) covers product grouping. Products can be grouped according to four different categories:

• Product family;
• Medical device system;
• Medical device system group (essentially a family of systems);
• Procedure packs.

The definitions used by the SFDA for grouping are generally aligned to those of other systems. However, grouping in one system may not directly translate to an acceptable grouping in the KSA, so you should independently evaluate SFDA grouping definitions.