

Medical Device Regulatory Updates

Dr. Doaa Saeed

General Manager of General Administration
of Medical Device Registration



Agenda

Egypt: regulatory updates Framework

First-Time Registration of Software as a Medical Device (SaMD) in Egypt

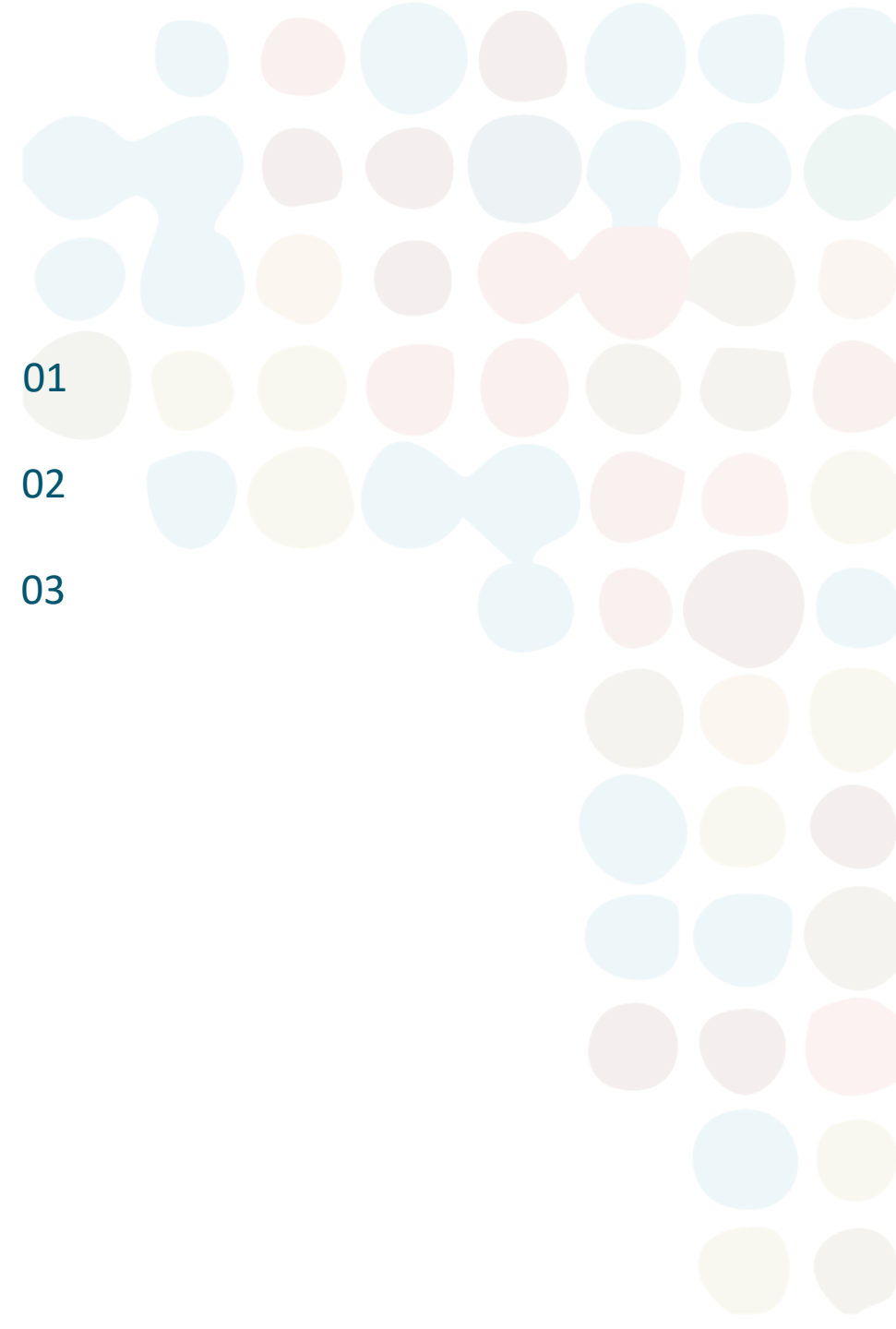
Facilitating the registration procedures regarding certificates submission

Exemption from submitting the ISO 13485:2016 certificate

01

02

03



Egypt: regulatory updates Framework

New Service

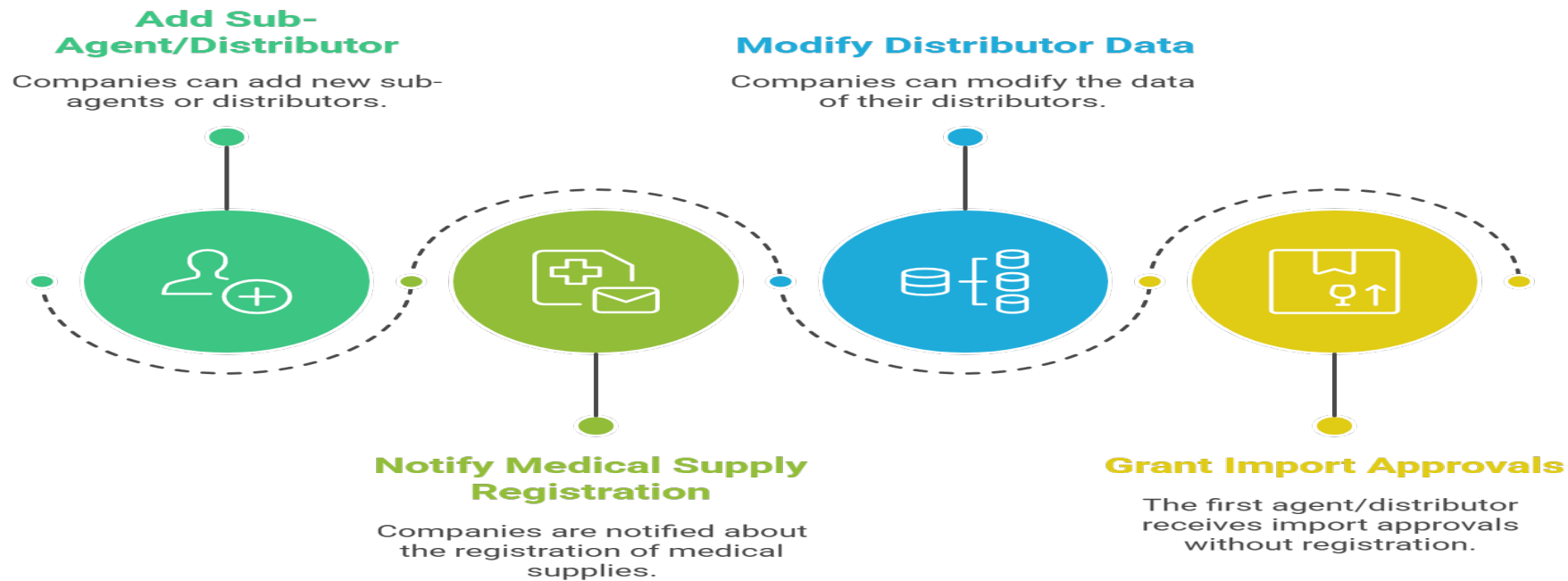
Announcement about a new service related to variables for medical supply companies.

American CFG Certificate

Announcement regarding medical devices with the American CFG certificate seeking import approvals.

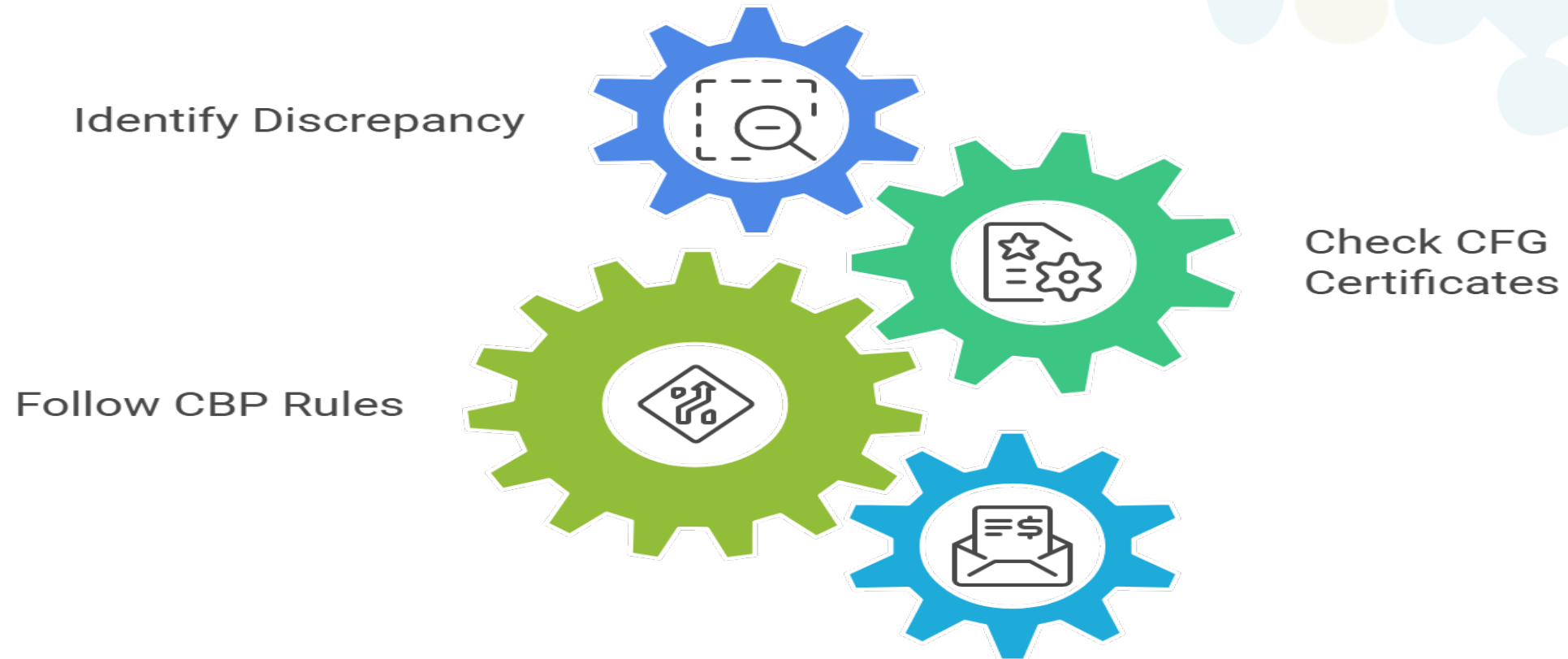
Egypt: regulatory updates Framework

A) New Service Introduction for adding a sub-agent / distributor



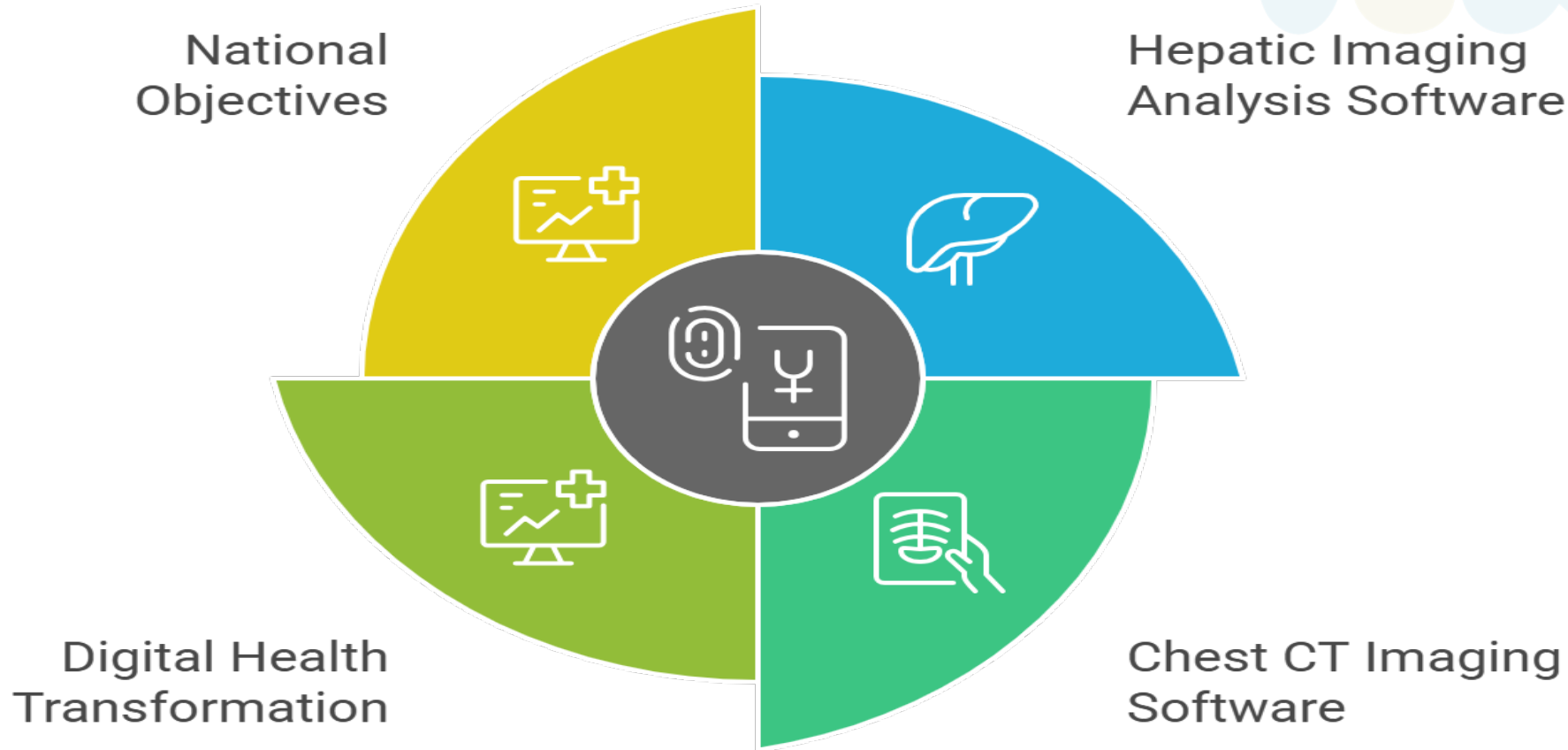
Egypt: regulatory updates Framework

B) Announcement regarding medical devices that have obtained the American CFG certificate



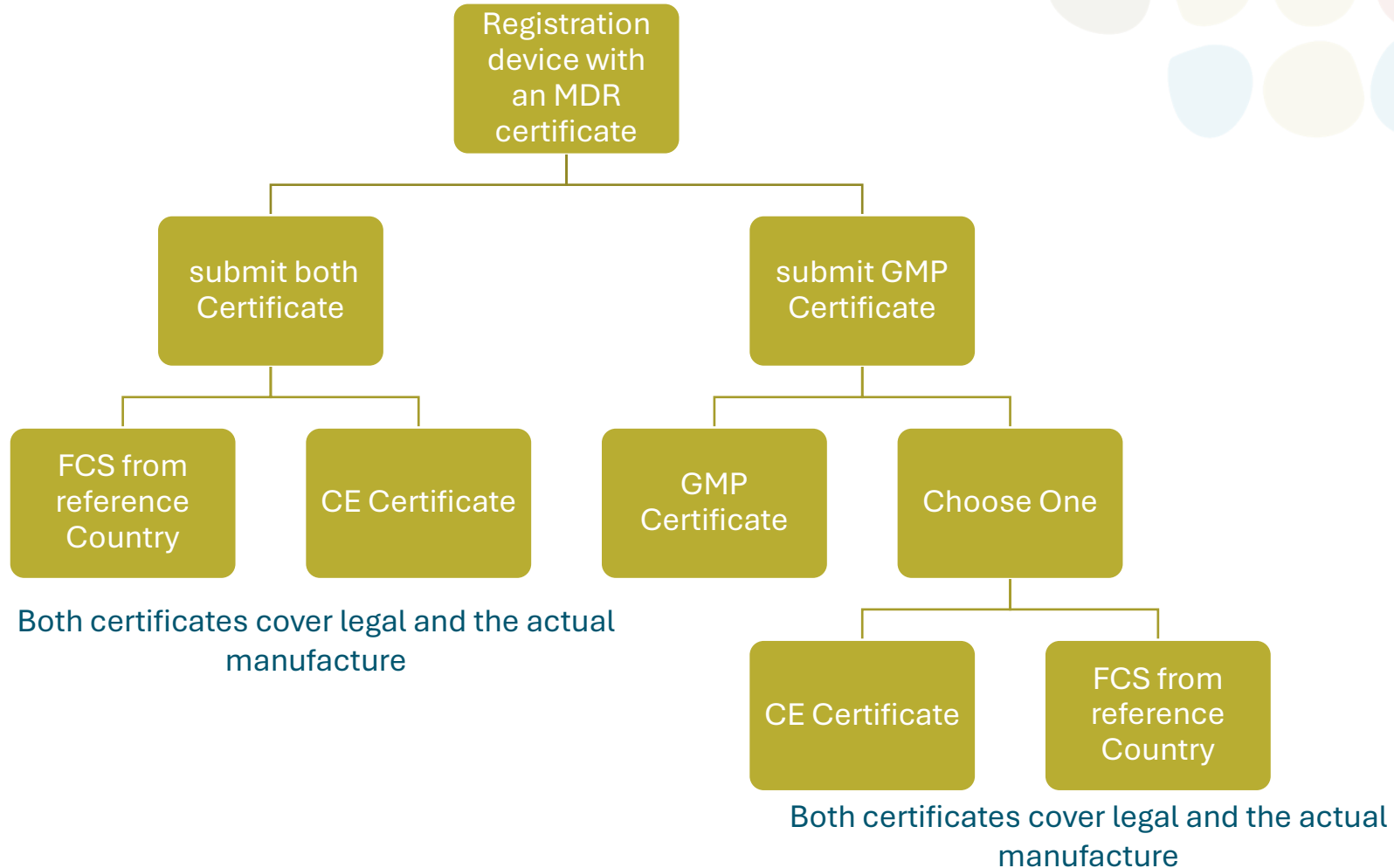
First-Time Registration of Software as a Medical Device (SaMD) in Egypt

Enhancing Diagnostic Accuracy and Clinical Decision-Making through Radiological Software for Hepatic and Chest CT (computed tomography) Imaging

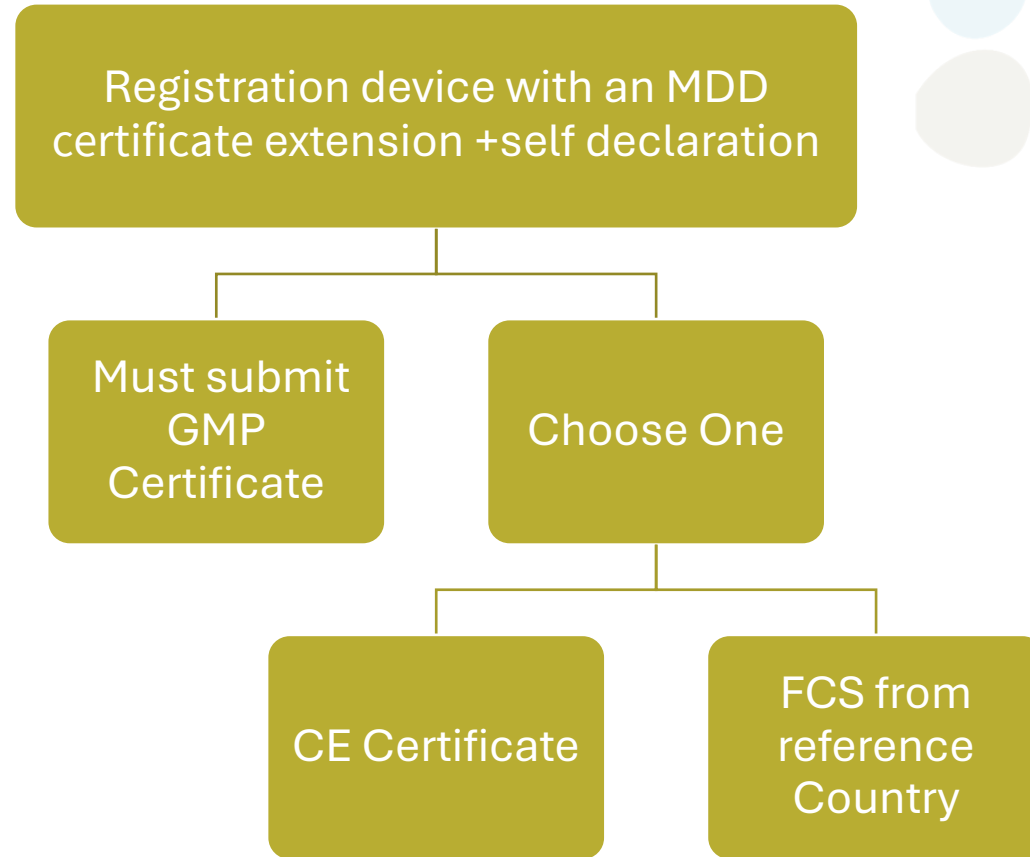


Facilitating the registration procedures regarding certificates submission

Exception of submitting the ISO 13485:2016 certificate



Exemption from submitting the ISO 13485:2016 certificate



Both certificates cover legal and the actual manufacture



For A Healthier Africa
AFRiSUMMIT

2nd - 5th November 2025

Hilton Grand Nile Hotel, Cairo - Egypt



هَيْئَةُ الدَّوَاءِ الْمِصْرِيَّةِ

THANK YOU