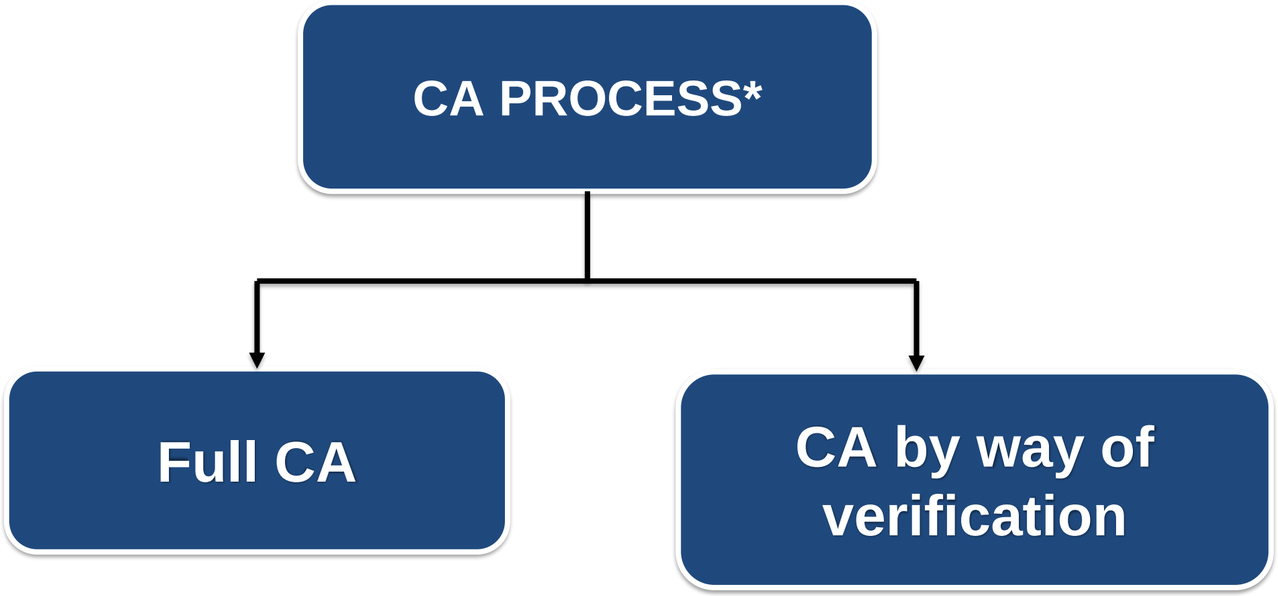
Conformity Assessment

- The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the EPSP of the medical device.
- Manufacturer must ensure that the medical device is safe and performs as intended and conforms to the EPSP for Medical Devices by conducting a CA procedures.



References:

- *Medical Device (Exemption) Order 2016*
- *MDA Circular Letter No.2/2014 Conformity Assessment Procedures for Medical Device Approved by Recognised Countries*

**Class A is exempted from conformity assessment procedure by a registered CAB*

CA Process & Parties Involved

Manufacturer conducts CA on 4 elements

QMS

- For manufacturer: ISO 13485
- For AR, importer, distributor: GDPMD

PMS System

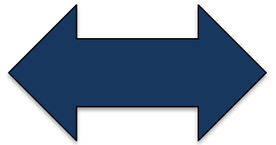
- Distribution record
- Complaint record
- Adverse incident reporting
- Field corrective action reporting

DoC

- A declaration made by the manufacturer of a medical device that the device is in conformity with the regulatory requirements
- DoC shall be signed by the manufacturer

Summary Technical Documentation

- Format –CSDT
- Compliance to EPSP
- Acceptable standards
- CAB determines the adequacy of the documented evidence to support attestation of conformity



CAB reviews evidence of conformity

Authority reviews & registers MD

Elements of CSDT

- ❑ Executive summary
- ❑ EPSP
- ❑ Description of MD
- ❑ Summary of design verification & validation documents
- ❑ Pre-clinical studies
- ❑ Software validation studies
- ❑ MD containing biological material
- ❑ Clinical evidence
- ❑ Use of existing bibliography
- ❑ MD labelling
- ❑ Risk analysis
- ❑ Manufacturer Information

CAB determines the adequacy of the documented evidence in support of the manufacturer's DoC to the EPSP through a review of the CSDT and technical documentation.

References:

- *MDA/GD/000 Common Submission Dossier Template*
- *MDA/GD/0004 Common Submission Dossier Template (CSDT) of IVD Medical Device*