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MDR AND THE APPLICATION PROCESS

Initial steps to certification

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GENERAL INFORMATION

Intertek Medical Notified Body
and the MDR Transition

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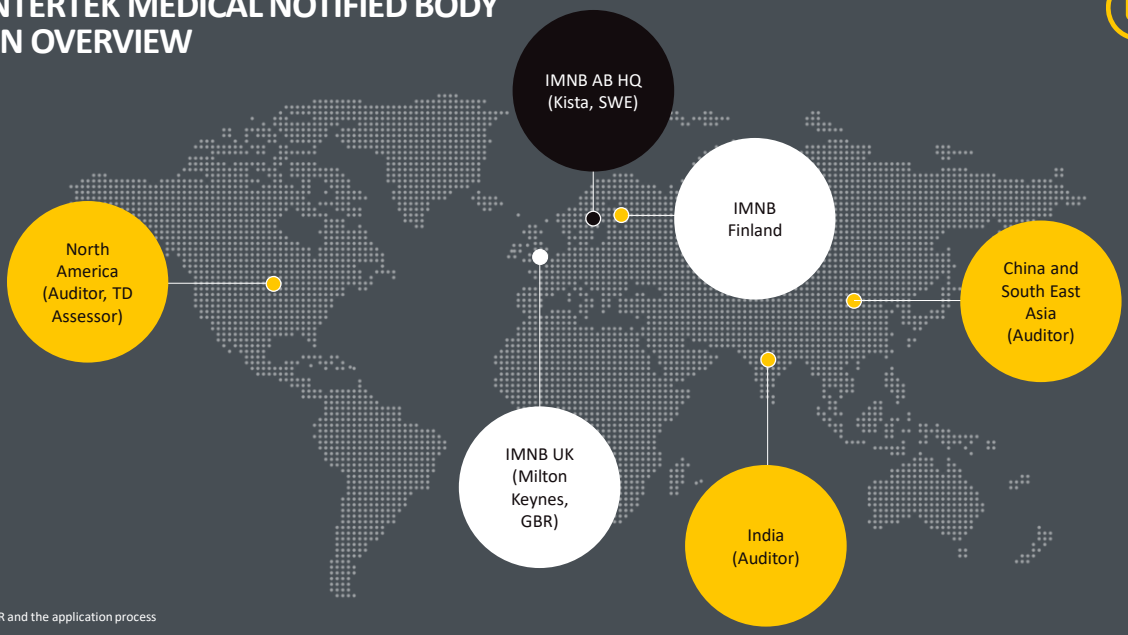
INTERTEK MEDICAL NOTIFIED BODY AN OVERVIEW



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IMNB SCOPE OF DESIGNATION (APPLIED FOR)

MDA	MDN	MDS	MDT
MDA 0201-MDA 0204 Active non-implantable devices for imaging, monitoring and / or diagnosis **MDA 0301 – MDA 03018** Active non-implantable therapeutic devices and general active non-implantable devices (except MDA 0304, 0309, 0310, 0314, 0317)	**MDN 1101 – MDN 1104** Non-active implants and long term surgically invasive devices **MDN 1201 – MDN 1214** Non-active non-implantable devices (except MDN 1206, 1207, 1212, 1214)	**MDS 1001** Devices incorporating medicinal substances (Article 117 devices only) **MDS 1004** Devices which are also machinery **MDS 1005** Devices in sterile condition **MDS 1006** Reusable surgical instruments **MDS 1008** Devices utilizing biologically active coatings… **MDS 1009** Devices incorporating software… **MDS 1010** Devices with measuring function **MDS 1011** Devices in system and procedure packs	All except of **MDT 2013** Devices which have undergone reprocessing

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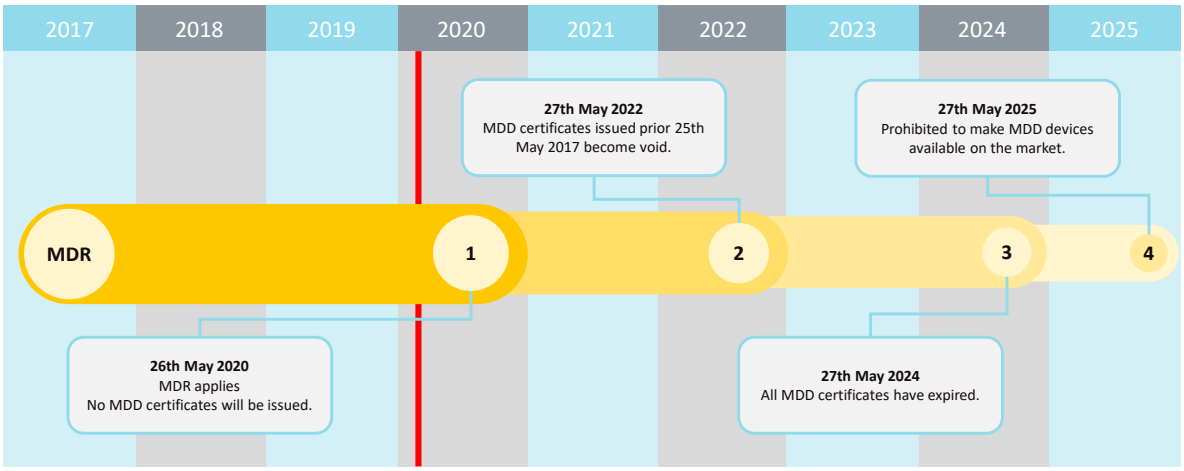
MDR TRANSITION
A BRIEF REMINDER



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MDR APPLICATION PROCESS

How to apply and what to consider?

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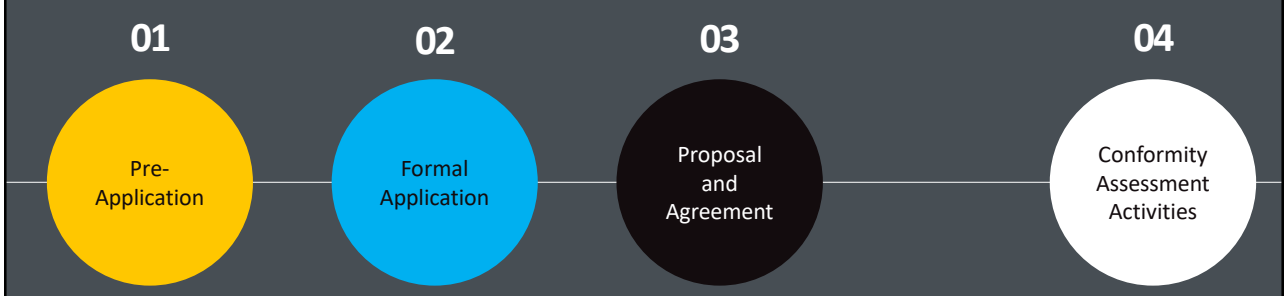
MDR APPLICATION PROCESS AN OVERVIEW



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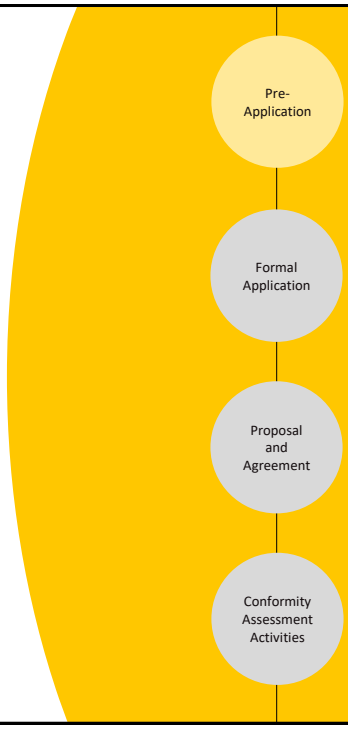
1. PRE-APPLICATION

Use of pre-application form via INTERTEK MEDICAL NOTIFIED BODY webpage

- Preliminary verification that
  - Device(s) are covered by MDR
  - Classification in acc. to MDR
  - Device(s) fall within MDR designation of IMNB
- Provision of budget estimate for potential client
- Choice to request a formal application package

Important considerations for manufacturer:

- Are my devices medical devices or devices w/o medical purpose in acc. to MDR? → MDR Article 2(1) and Annex XVI
- What classification do my devices have? → MDR Annex VIII
- What codes are applicable for my corresponding types of devices → EU Regulation 2017/2185
- Is my Notified Body of choice designated for my devices? → NANDO



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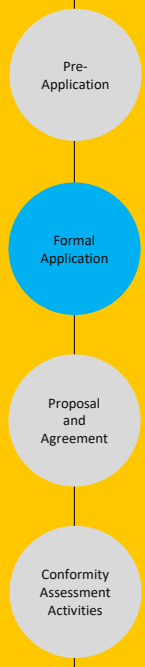

2. FORMAL APPLICATION

Complete Client Information Form (CIF) and Device List

- Final verification of
  - Manufacturer's Information (Legal manufacturer, Authorized representative, Distributor, etc.)
  - Management System Information (Scope of certification, Sites, Processes, Suppliers, etc.)
  - Medical Device Information (Basic UDI-DI, Class, MDA/MDN, MDS, MDT, **EMDN**, etc.)
  - Capacity and Coverage by IMNB (Designated for devices, Sufficient competencies, etc)

Important considerations for manufacturer prior to formal application:

- What is my role and what are my obligations in acc. to MDR?
- How is my organisation and my QMS structured, organised, managed?
- Have I assigned UDIs to the devices?
- How are my devices classified and categorised?
- Have I made myself familiar with the new coding systems (MDA/MDN, MDS, MDT, EMDN)?
- Is my QMS and are my Technical Documentations in full compliance with MDR requirements?

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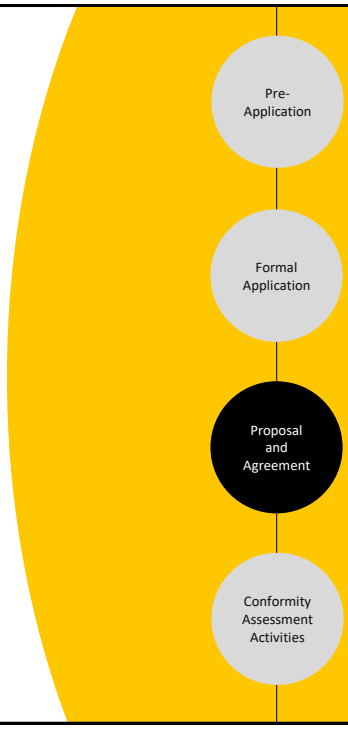
3. PROPOSAL AND AGREEMENT

Specifies:

- Scope of certification
- Audit criteria
- Number of TD assessments prior certification
- Audit days prior certification and surveillance
- Rights and obligations of manufacturer and Notified Body

→ The proposal will automatically turn into an agreement as soon as the manufacturer and IMNB have signed it.



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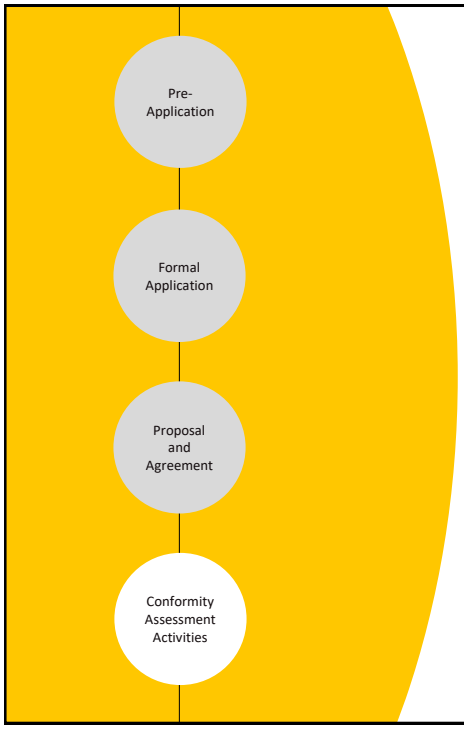

4. CONFORMITY ASSESSMENT ACTIVITIES

PRIOR INITIAL CERTIFICATION

- Technical Documentation Assessment
  - Number of assessment depends on number of categories of devices (IIa), generic device groups (IIb), devices (IIb implants and III)
  - Sampling of at least one (1) device per category, device group
- Initial certification audit
  - Number of audits depending of number of sites
  - Audit performance after 1st round of all initial TD assessments performed

SURVEILLANCE

- Technical Documentation Assessment
  - Number of assessments depends on number of devices in each category, generic device group
  - Sampling has to cover entire range of products during validity period of certificate
  - If only few devices and these have been assessed further sampling will focus on PMS during audits
- Surveillance audits
  - Annual surveillance (at least 4 surveillance audits prior re-certification)

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SURVEILLANCE AND CHANGES UNDER MDD

Activities during transition period?

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SURVEILLANCE UNDER MDD LATEST UNTIL 26TH MAY 2024

Surveillance Audits (MDD)	Technical Documentation Assessment (MDD)	Post Market Surveillance (MDD)
Continued as normal Annual surveillance (can be done parallel to MDR audits → will add time to the audit)	Focus on PSUR. Sampling still possible.	**Even for MDD manufacturers:** Conformity with MDR requirements related to PMS, market surveillance, vigilance necessary Use of new MIR Form mandatory Use of IMDRF coding mandatory

NOTIFICATION OF CHANGES UNDER MDD

ALL reportable changes shall still be reported to IMNB even for MDD certificates

Changes requiring update of certificate or additional conformity assessment activities will NOT be accepted under MDD, e.g.:

- Changes in scope statements
- Design changes
- Change of intended use/purpose
- Addition of new products

→ For these changes MDR certification might be required

Changes with NO impact on MDD certification might be accepted

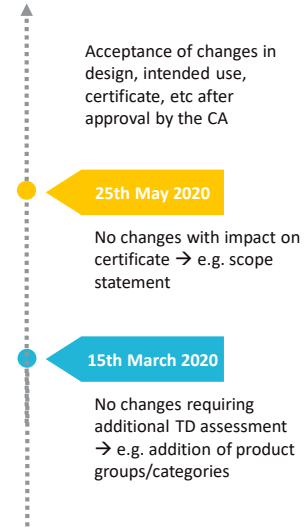

Figure: IMNB's policy for changes under MDD

When can we apply?

Immediately after designation. Will be published in NANDO database. We will send out a client communication. However, please only apply when your TD is ready to be assessed. Otherwise, we might have to reject your application.

When can we have our first audit against MDR?

After the application is sufficiently completed by manufacturer and after all 1st rounds of initial TD assessments prior certification have been performed. Client can also express wish to align initial MDR audit with other audit cycles (possible when requirements above are fulfilled).

How long after the application will we have a certificate?

Highly dependent on the structure of TD, number of required TD assessments, novelty of devices, etc. That means it is mostly dependent on amount of time for TD assessment and our availability.

How will you handle the audits for MDD and MDR if you have a certificate for both?

We will try to combine these but we will have to add time to the combined audits. Otherwise, we have to perform separate audits.

How will you prioritize current clients in the transfer to MDR?

We have a waiting list. We need to handle all clients as new clients. However, current MDD clients will be prioritized over new clients.

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