

MDR APPLICATION PROCESS

01

PRE-APPLICATION

During the pre-application phase, you will be asked to provide basic information on your company and on your devices in the Client Information Form (CIF) and Device List.

It is important to provide accurate information at this stage to ensure a smooth application process later.

02

PROPOSAL AND AGREEMENT

Based on the information provided during the pre-application, Intertek Medical Notified Body (IMNB) will prepare and send you a proposal for our MDR Conformity Assessment services.

If you select IMNB as your Notified Body for MDR conformity assessment, you must sign and return the agreement.

By signing the proposal, you confirm that the legal address and scope of certification are correct. Any change made after signing the proposal will be handled through the change management process.

03

03 FORMAL APPLICATION

The signature of the proposal and agreement will kick off the formal application process.

During the formal application process, you will be asked to provide additional information and more detailed information in the device list if you have not done so earlier during the pre-application process.

Please note that Intertek Medical Notified Body only accepts documentation in English

FOR MORE INFORMATION

