

# MDR APPLICATION PROCESS

01

## PRE-APPLICATION

- Before formally applying, you must\* complete a pre-application form with basic information regarding your company and your device(s) that will be assessed and considered.
- The pre-application includes an option to request a formal application or a budget estimate which will be based on the information provided.

\* This is optional for our current clients under MDD. Please contact us at [IMNB@intertek.com](mailto:IMNB@intertek.com) for more information.

02

## FORMAL APPLICATION

- If you opted for a formal application, we will send you a client information form (CIF). The CIF will ask you to provide further information about your company and devices. We will provide a guidance document to you on how to complete the CIF.
- If you opted for a budget estimate, we will send it to you separately.
- Your submitted CIF will be reviewed, and we may contact you to ask for further information or clarification.
- Please note that Intertek Medical Notified Body only accepts documentation in English.

03

## PROPOSAL AND AGREEMENT

- After the CIF is assessed and approved by Intertek Medical Notified Body (IMNB), a proposal and certification agreement will be sent to you for consideration.
- The proposals and agreements are to be signed by you and countersigned by IMNB, and a copy is then sent to you by email. Please note: By signing the proposal you ensure that the legal address and scope of certification are correct. Any changes from your side after signing the proposal are to be handled separately.
- All aspects of the conformity assessment activities related to initial certification will be communicated separately to the client once the application is approved and agreements signed.
- Communication with IMNB regarding MDR should be sent to: [IMNB@intertek.com](mailto:IMNB@intertek.com)