

# 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.

**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.
- By submitting the CIF, you agree to the application fee as found in the current price list.
- 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), an invoice for the application fee and a proposal and certification agreement will be sent to you for consideration. We will not begin any formal certification conformity activities until we have received the application fee.
- 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, the application fee is paid, and agreements signed.
- Communication with IMNB regarding MDR should be sent to: [IMNB@intertek.com](mailto:IMNB@intertek.com)