

Your IVDR application to BSI

Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI of (EU) 2017/746, IVDR.

One reason for delays in a notified body review is receiving an incomplete submission, where we have not received all the information needed during the application process. So, to ensure you submit all the required information, please find a list of documents that we will be looking to receive:

- Sample draft Declaration of Conformity (as per Annex IV of IVDR) for the highest classification device included in the application
- Quality Policy
- Quality Objectives
- Quality Manual
- Post Market Surveillance (PMS) procedure
- Sample PMS plan for the highest classification device (or groups of devices) included in the application
- Vigilance reporting procedures covering incident reporting, field actions, periodic summary reporting, and trend reporting
- A description of the procedures in place for keeping PMS plans, Post Market Performance Follow-up (PMPF) and vigilance procedures up to date
- Sample Performance Evaluation plan for the highest classification device (or groups of devices) included in the application
- Procedures for keeping the Performance Evaluation plans up to date taking into account the state of the art
- Sample PMPF plan for the highest classification device (or groups of devices) included in the application

For self-testing, near-patient testing devices that are class B, class C or class D, if practicable and required, BSI may request an example of the device during the conformity assessment process.

bsi.

Talk to BSI today

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