



The STED* should include the following device descriptive information:

- A general description of the device including its intended use/purpose;
- The intended patient population and medical condition to be diagnosed and/or treated by the device and other considerations such as patient selection criteria;
- The principles of operation of the device;
- The Class of the device and the applicable classification rule
- An explanation of any novel features;
- A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the device;
- A description or complete list of the various configurations/variants of the device that will be made available;
- A general description of the key functional elements of the device, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include: labelled pictorial representations of the device (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.
- A description of the materials incorporated into key functional elements of the device and those making either direct or indirect contact with a human body.

-Specifications:

A list of the features, dimensions and performance attributes of the medical device, its variants and accessories (if such are within the scope of the STED), that would appear typically in the product specification made available to the end user.

**Summary of technical documents*

General Secretariat
National Medicines and Poisons Board