Device Description Checklist

Device Name/ Model Name

Sl.no	Checklist Point	Comments	Present/ Absent
Device description and specification			
1.	Product or trade name and a general description of the device including its intended purpose and intended users;		
2.	The Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;		
3.	The intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;		
4.	Principles of operation of the device and its mode of action, scientifically demonstrated if necessary;		
5.	The rationale for the qualification of the product as a device;		
6.	The risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;		

7.	An explanation of any novel features;		
8.	A description or complete list of the various configurations/variants of the device that are intended to be made available on the market;		
9.	A description or complete list of the various configurations/variants of the device that are intended to be made available on the market;		
10.	A general description of the key functional elements, e.g. Its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. Diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;		
11.	A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;		

12.	Technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.		
Reference to previous and similar generations of the device			
13.	An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;		
14.	An overview of identified similar devices available on the Union or international markets, where such devices exist.		