1	Medical Device Information (MEDDEV A3)	n/a	Yes	No	Remarks
1.1	Device Description name, models, sizes, components of the device, including software and accessories	☐	☐	☐	
1.2	Intended purpose of the device, including: - exact medical indications (if applicable), contraindications - name of disease or condition/ clinical form, stage, severity/ symptoms or aspects to be treated, managed or diagnosed - patient populations (adults / children / infants, other aspects) - intended user (use by health care professional / lay person) - organs / parts of the body / tissues or body fluids contacted by the device - duration of use or contact with the body, invasiveness - repeat applications, including any restrictions as to the number or duration of re-applications - contact with mucosal membranes/ invasiveness/ implantation - single use / reusable	☐	☐	☐	
1.3	General description of the medical device, including (non-exhaustive): - a concise physical and chemical description - the technical specifications, mechanical characteristics - applicable standards - sterility, radioactivity, … - how the device achieves its intended purpose - principles of operation - materials used in the device with focus on materials coming in contact (directly or indirectly) with the patient/ user, description of body parts concerned - whether it incorporates a medicinal substance (already on the market or new), animal tissues, or blood components, the purpose of the corresponding component - For devices based on predecessor devices: Name, models, sizes of the predecessor device, whether the predecessor device is still on the market, description of the modifications, date of the modifications.	☐	☐	☐	
1.4	Alternative methods of treatment / Description of therapies	☐	☐	☐	