## Appendix A

Cross-references between requirements in Annex XV chapter II of the MDR and the Clinical Investigation submission package

Prior to submission of the IB, sponsor may complete this checklist to ensure the IB meets the minimum requirements for validation of the application per article 70 of the MDR.

The checklist, if used, should be included together with the IB in the submission to facilitate the validation by the competent authority.

| **Cross-references between requirements in Chapter II Annex XV of the MDR and the Clinical Investigation submission package** | | | |
| --- | --- | --- | --- |
| **Requirement** | | **Description of requirement** | **Location within submission package** |
| Annex XV Chapter II (2):  **Investigators Brochure** (information in IB or enclosed as separate documents with a summary provided in the IB.  If enclosed as separate documents, a clear reference within the IB should be made to the enclosed documents) | 2.1 | Identification and description of the device | Document Page |
| 2.1 | Identification of the device | Document Page |
| 2.1 | Information on the intended purpose | Document Page |
| 2.1 | The risk classification and applicable classification rule pursuant to Annex VIII | Document Page |
| 2.1 | Design of the device | Document Page |
| 2.1 | Manufacturing of the device | Document Page |
| 2.1 | Reference to previous and similar generations of the device. | Document Page |
| 2.2 | Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements | Document Page |
| 2.2 | Information to be placed on the label | Document Page |
| 2.2 | Instructions for use to be provided with the device. | Document Page |
| 2.2 | Information relating to any relevant training required. | Document Page |
| 2.3 | Pre-clinical evaluation based on pre-clinical testing and experimental data in particular as applicable;  in-design calculations, in-vitro test, ex-vivo test, animal test, mechanical test, electrical test, reliability test, sterilization validation, software verification and validation, performance test, evaluation of biocompatibility and biological safety.  Summary and evaluation of pre-clinical/ non-clinical data | Document(s) Page |
| 2.4 | Existing clinical data, in particular available literature or other clinical data available relating to safety, performance and clinical benefit | Document Page |
| 2.5 | Summary of the benefit risk analysis and risk management | Document Page |
| 2.5 | Information regarding known or foreseeable risks, any undesirable side effects, contraindications and warnings | Document Page |
| 2.6 | In case of devices that contains:  **medicinal substance**  Detailed information om the substance, and the risk management in relation to the substance, and evidence for the added value of incorporation of such constituents in relation to the clinical benefit and safety of the device | Document Page |
| 2.6 | In case of devices that contains:  **human blood / plasma or derivate**  Detailed information om the substance, and the risk management in relation to the substance, and evidence for the added value of incorporation of such constituents in relation to the clinical benefit and safety of the device | Document Page |
| 2.6 | In case of devices that contains  **non-viable tissues or cells of human or animal origin, or their derivatives**  Detailed information on the tissue/cell their derivate, and the risk management in relation to the tissue, cell or their derivate, and evidence for the added value of incorporation of such constituents in relation to the clinical benefit and safety of the device | Document Page |
| 2.7 | List of fulfilment of the General Safety and Performance Requirements (GSPR).  A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking. | Document Page |
| 2.8 | A detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice. | Document Page |