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| **CHECKLIST FOR EC DECLARATION OF CONFORMITY (ANNEXVII)**  (amended as per 2007/47/EU) | | | |
| **Manufacturer’s Name and Address:** |  | | |
| **Type and Name(s) of Medical Device(s):** |  | **Classification according to the MDD, Annex IX:** |  |
| **File No.:** |  | **File name/location/path as relevant:** |  |
| **Date:** |  | **Prepared by/signature:** |  |

| **TECHNICAL DOCUMENTATION** | | | | |
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| **#** | **Reference** | **Documentation requirement** | **Manufacturer’s Compliance Documentation** | **Compliance** |
| 1 | Annex VII, section 3, 1st - | General description of the product type and intended use(s) (including any variants) and a clarification of the classification according to Annex IX. | OK |  |
| 2 | Annex VII, section 3, 2nd - | Design drawings, manufacturing methods, diagrams of components, sub-assemblies, circuits, etc. | OK |  |
| 3 | Annex VII, section 3, 3rd - | Functional product descriptions, explanatory descriptions necessary to understand the above mentioned drawing and diagrams and the operation of the product | OK |  |
| 4 | Annex VII, section 3, 4th - | Conformance to the essential requirements of Annex I (including list of harmonized standards applied, specifying whether used in full or in part), including solutions adopted when not applying the harmonized standards in full | OK |  |
| 5 | Annex VII, section 3, 4th - | The results of the risk analysis (risk management file). | OK |  |
| 6 | Annex VII, section 3, 5th - | For sterile products, descriptions of the methods used and the validation report. | OK |  |
| 7 | Annex VII, section 3, 6th - | Results of the design calculations and inspection activities. | OK |  |
| 8 | Annex VII, section 3, 6th - | Technical test results (electrical safety test, mechanical safety test, EMC test (emission & immunity), etc.). | OK |  |
| 9 | Annex VII, section 3, 6th - | Furthermore a description verifying that the essential requirements are adhered to when connecting devices which are specified by the manufacturer. |  |  |
| 10 | Annex VII, section 3, 7th - | The risk control option analysis (e.g. as per EN ISO 14971:2007, section 6.2) |  |  |
| 11 | Annex VII, section 3, 8th - | Pre-clinical evaluation |  |  |
| 12 | Annex VII, section 3, 9th - | Clinical evaluation in accordance with Annex X concerning "Clinical Evaluation" (and MEDDEV 2.7.1.) |  |  |
| 13 | Annex VII, section 3, 10th - | Labeling (marking on the device, marking on the packaging and the CE-marking itself). |  |  |
| 14 | Annex VII, section 3, 10th - | Instructions for Use and other information for the user (Annex I, section 13) must be in compliance with national requirements of the member state(s) in which the device will be placed on the market (refer Article 4 item 4). |  |  |

| **QUALITY SYSTEM DOCUMENTATION** | | | | |
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| **#** | **Reference** | **Documentation requirement** | **Manufacturer’s Compliance Documentation** | **Compliance** |
| 15 | Annex VII section 4 | Procedure for registration and implementation of corrective actions following the post-production phase, including information according to Annex X, section 1.1.c. Actions concerning the Competent Authorities should be established for:  (i): Any malfunctions which might lead to 1) the death of a patient or user or 2) a serious deterioration of his state of health.  (ii): any technical or medical malfunction which has resulted in a systematic recall from the market. |  |  |
| 16 | Annex VII section 5, 1st - | **Sterile Class I devices:** The procedures of Annexes II, IV, V and VI also applies for this class of devices. It only concerns the sterility requirements of these Annexes. |  |  |
| 17 | Annex VII section 5, 2nd - | **Class I devices with a measuring function:** The procedures of Annexes II, IV, V and VI also apply for this class of devices. It only concerns the metrological requirements of these Annexes. |  |  |