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| **CHECKLIST FOR EC DESIGN-EXAMINATION (ANNEX II, §4)** | | | |
| **Manufacturer:** |  | | |
| **Product Type & Name:** |  | **Product classification accor­ding to Annex IX of the MDD (IIb or III) and rule(s) applied:** |  |
| **Case No.:** |  | **File name/location*:*** |  |
| **Date:** |  | **Prepared by:** |  |

| **TECHNICAL DOCUMENTATION** | | | | |
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| **#** | **Reference** | **Documentation requirement** | **Manufacturer's Compliance Documentation** | **Compliance** |
| 1 | §3.1, 1st indent | Name and address of the manufacturer and any additional manufacturing site covered by the quality system | (may be part of the change notification, if so replace this guidance by a reference to the change notification prepared, e.g. date of change notification and name of individual signing the change notification) |  |
| 2 | §3.1, 2nd indent | The documentation described in §4.2 (refer to items with reference “§3.2(c), xth indent” further down in this checklist) |  |  |
| 3 | §3.1, 3rd indent | A written declaration that no application has been lodged with any other notified body for the same product-related quality system (may be part of change notification) | (may be part of the change notification, if so replace this guidance by a reference to the change notification prepared, e.g. date of change notification and name of individual signing the change notification) |  |
| 4 | §4.2  (§3.2(c) 1st indent) | General description of the product and intended use (including variants) and a clarification of the risk classification according to Annex IX. |  |  |
| 5 | §4.2  (§3.2(c) 2nd indent) | Design specifications (incl. standards applied). |  |  |
|  | §4.2  (§3.2(c) 2nd indent) | The results of risk analysis (risk analysis, risk control incl. validation and risk acceptability decision, i.e. risk management file) carried out. |  |  |
|  | §4.2  (§3.2(c) 2nd indent) | Compliance with the essential requirements of Annex I. For ER’s not covered or not fully covered by a harmonized standard, a description of the solutions adopted to fulfill such requirements. |  |  |
|  | §4.2  (§3.2(c) 3rd indent) | The verification and validation results used to compare the product design against the design specification (electrical safety test, mechanical safety test, EMC test (emission & immunity), etc.). |  |  |
| 6 | §4.2  (§3.2(c) 4th indent) | A validation for system combinations and their compliance with the Essential Requirements of Annex I. |  |  |
| 7 | §4.2  (§3.2(c) 5th indent) | A statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in section 7.4 of Annex I, and (if so) the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device. | (may be part of the change notification, if so replace this guidance by a reference to the change notification prepared, e.g. date of change notification and name of individual signing the change notification) |  |
| 8 | §4.2  (§3.2(c) 6th indent) | A statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC. | (may be part of the change notification, if so replace this guidance by a reference to the change notification prepared, e.g. date of change notification and name of individual signing the change notification) |  |
| 9 | §4.2  (§3.2(c) 7th indent) | The solutions adopted as referred to in Annex I, chapter I, section 2.  [The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the general acknowledged state of the art.  In selecting the most appropriate solution, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (Inherent safe design and construction), - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, - inform the user of the residual risks due to any shortcomings of the protection measures adopted.] |  |  |
| 10 | §4.2  (§3.2(c) 8th indent) | The pre-clinical evaluation |  |  |
| 11 | §4.2  (§3.2(c) 9th indent) | The clinical evaluation referred to in Annex X concerning "Clinical Evaluation" (as per the current version of MEDDEV 2.7.1). |  |  |
| 12 | §4.2  (§3.2(c) 10th indent) | The (draft, if final version is not yet available) label, (marking on the device, marking on the packaging and the CE-marking itself). |  |  |
| 13 | §4.2  (§3.2(c) 10th indent) | (Draft, if final version is not yet available) instructions for use (and other information for the user concerning e.g. installation, if the installation is to be performed by user/operator) which must be in compliance with the national language requirement(s) in the countries where the product is placed on the market (refer to the MDD, article 4, section 4). |  |  |
| **QUALITY SYSTEM DOCUMENTATION** | | | | |
| 14 | §4.4 | Procedure to inform the Notified Body and update the EC Design Examination certificate in case of **any** change to the approved product. |  |  |

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