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| **Company name and Address** | | |
| **Device Identification and Technical Documentation ID** (repeat in page headers)  [Title] | | |
| **Description of the Device** | | |
| **Range of Devices (models) covered by checklist** | | |
| **Classification + Rule** | | |
| **NBOG MDA Code and/or EMDN Number** | | **Basic UDI-DI of the device** |
| **Checklist ID and Revision No** (repeat in page headers)  [Subject] | | |
| **Prepared by** | **Approved by** | **Date checklist approved** (repeat in page headers)**:**  [Publish Date] |

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| **I** | **GENERAL REQUIREMENTS** |  |  |  |  |
| 0 | Administration | ☐ Technical documentation to be subject to document control: indexed, page numbers, authorized.  ☐ For devices previously reviewed by Notified Body provide TD change history identifying all changes since last review with reason for why change was needed and benefit.  ☐ Covering letter including Table of Contents  ☐ The Technical Documentation in electronic form is recommended to be formatted according to IMDRF Table of Contents (ToC) format, please see IMDRF/RPS WG (PD1)/N27R2  ☐ The [Team-NB’s Best Practice Guidance for Technical Documentation](https://www.team-nb.org/wp-content/uploads/members/M2022/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-V1-final.docx) has been applied  ☐ In case of Voluntary change of NB, provide previous NB certificate and report.  Details of the EU representative if legal manufacturer is located outside of EU |  |  |  |
| 1 | Device description, specifications | Device description includes  Product name, possible marketing name, description, intended purpose and intended users for all the variants covered by TD  Group of variants in the TD  Product identification including Basic UDI-DI, European Medical Device Nomenclature description and code, Implementing regulation 2017/2185 codes and associated rationale  Principles of operation and mode of action, i.e Description of how device is used – alone or in combination with other devices or accessories. General description of the key functional elements  Marketing brochure/materials  List of all accessories  Product classification with justification  Clinical assessment route chosen (Literature, clinical investigation, Literature & Investigation,  (MDR Article 61, Section 10)  Literature search protocol with databases to use, search terms, filters to use, inclusion/exclusion criteria, weighting  Documentation of Clinical, biological and technical equivalence, if equivalence claimed for safety & performance  Clinical hazards identified and included in risk management documents  Copies of literature  Clinical evaluation report, with a critical evaluation of relevant clinical data and how these data support the GSPRs, the performance claims and safety  CVs and Declarations of Interest  Technical and (raw) material specification, description of key functional elements and any novel features  Specified package shelf life  Specified device life in use  Overview of previous generations of the device, if applicable  Overview of similar devices available, both in the EU and elsewhere  Statements on absence/presence of TSE species derived materials which may also be used in manufacturing processes. Is regulation 722/2012 applicable? Yes or no – provide justification  Statements on absence/presence of medicinal substances according to Directive 2001/83/EC  Statements on absence/presence of human blood derivatives  Statements on absence/presence of phthalates in device or other products that could leak from the device that may be carcinogenic, mutagenic or toxic | Include product variants, accessories and options in the description. Use the intended price list as a guidance what is to be included.  Functionality of the device must be given at a level that it is possible to evaluate the claims, including performance and principle of operation.  For SW this means description of operation, architecture, plans, figures and drawings. | Document name revision, date, page/chapter |  |
| 2 | Information to be supplied by the manufacturer | EU Declaration of Conformity (unequivocally identify all variants/models covered by the DoC, all applicable directives and/or regulations)  Instructions for Use and other Labeling in the languages accepted in the Member States where the device is envisaged to be sold or justification if no IFU supplied  Complete set of labels, including markings on the device, unit pack, sales pack, transportation pack when applicable  Use of symbols  Labeling information consistent with other TD documents including Risk Management & Clinical Evaluation  Verification of translated documents  Other relevant documentation e.g. implant card (article 18 if relevant), e-labeling | See Annex I, chapter III – Requirements Regarding the Information Supplied with the Device (GSPR 23)  Labeling must be available in all the EU languages that are required by the intended markets.  Note: In the QMS there must be a process for identifying and creating correct language versions.  See Annex IV for the required contents of EU Declaration of Conformity. |  |  |
| 3 | Design and manufacturing information | Information to allow key design stages to be understood (design planning, input, output, review, verification, validation, transfer, changes)  Detailed description of manufacturing processes  Manufacturing validations, monitoring and  final product testing  Identification of all manufacturing sites, suppliers and sub-contractors, sterilization provider, external testing facilities undertaking design or manufacturing verification and/or validation processes for the manufacturer. Detail of accreditation/certification/qualification to be provided.  Specifications/drawings/Bill of Materials for the critical components and finished manufactured device  Specifications used in manufacturing e.g. for components, sub-assemblies, raw materials, packaging, etc.  Sterile devices – supplier specifications demonstrating suitability of the sterile barrier for the sterilization process that will be used.  Documentation to show the device will meet its specification after storage and transportation/shipping  Defined storage conditions | Process descriptions, procedures, design phases including design reviews, test reports. |  |  |
| 4 | General safety and performance requirements | Evidence of conformity with the Safety and Performance Requirements set out in Annex I, including:  Identification of applicable SPRs  Methods used to demonstrate conformity  Applicable standards, Common  Specifications or other requirements  Links to documents demonstrating  conformity with SPRs | Justifications required if a key standard is not used, standards are only partially used, or the latest version of a standard is not used which would demonstrate the State of the Art. |  |  |
| 5 | Benefit-risk analysis and risk management | Benefit-risk analysis as required by GSPRs 1 and 8  Solutions adopted and results of Risk Management as required by GSPR 3 | GSPR 1 & 8: benefits > risks, risks reduced as far as possible and acceptable in light of the  current state of the art  GSPR 3: outlines the key clauses of ISO  14971:2019 and EN ISO 14971:2019/A11:2021  Description fo risk management methods  Risk Matrix, Risk Log (RMF)  Risk Management Plan and Report (Note: Requires Summary and evaluation of Residual Risk) |  |  |
| 6 | Product verification and validation | Verification test results:  Biocompatibility data (See EN ISO 10993-1:2020)  Physical, chemical, microbiological characterization  Electrical safety  EMC  Software V&V (IEC 62304, IEC 82304-1, MDCG 2019-11)  Cybersecurity (MDCG 2019-16, Team-NB Position Paper CyberSecurity-V1)  Stability, shelf life  Documentation to show the device will meet its specification at the end of its in-use life, including required level of cleanliness or sterility  For sterile devices documentation to show the device and the device pack will remain sterile and in specification after (specified) worst-case sterilization process, and at the end of the pack shelf life  Performance verification  Pre-clinical and clinical testing  Report demonstrating device compatibility with any substance that can come into contact with the device e.g. fluids, medicinal substances  Information on how product cleanliness requirements are met e.g. controlled environment, device cleaning processes, bioburden  Device test reports e.g. to demonstrate compliance to GSPR, finished device specification, claims made, Standards met, verification of Performance Claims  Validation data:  Clinical evaluation plan  Clinical Evaluation Report  Clinical Investigation documents demonstrating requirements of Annex XV (where conducted)  Protocol  Letter of no objection/approval  Local ethics committee approval  Clinical investication report  Details of any adverse events in the investigation  Summary of Safety and Clinical Performance (SSCP) – (if relevant – implantable devices and class III devices)  CECP (clinical evaluation consultation procedure)  Usability data (EN 60601-1-6, EN 62366-1)  Validation documents for critical manufacturing processes that can affect final product quality e.g. molding, gluing/ bonding, cleaning, sterile barrier sealing, etc  PMCF plan and evaluation report (MDCG 2020-7, MDCG 2020-8)  PMS Plan and Report  Specific validations for devices incorporating medicinal substances, animal or human tissues, CMR or endocrine-disrupting substances, absorbable devices, sterile devices, devices with measuring function, devices used in combination  Additional information required is specific cases:  Medicinal product safety data  Human/animal tissue safety data  Compound/substance safety data  Justification for CRM or endocrine-disrupting substance  Additional information required in case the device supplied sterile or to be sterilized by user  Sterile devices – documentation demonstrating how  Sterilization Standards are considered – EN ISO 11135, EN ISO 11137-1, EN ISO 11137-2, EN ISO 17665-1, EN ISO 13408 series  Devices supplied non-sterile for sterilization by user – validation documentation for sterilization/reprocessing instructions  Technical agreement with sub-contractors – device manufacturer and sterilization company  Determination of bioburden – validation for test method, and 2 most recent bioburden results  Manufacturing environmental controls  Sterility testing – validation of test method  Ethylene Oxide EO sterilization documents to include validation protocol, validation report, residuals report, information on EO gas specification, biological indicators, last requalification review  Radiation sterilization documents to include dose setting/ dose substantiation (e.g. Method 1, VDmax & if conducted  for a product family rationale for the device being in the family), 2 most recent dose audit reports, process validation protocol and report (dose mapping & if done for a processing category rationale for the device being in the processing category)  If device also meets the definition of Machinery per 2006/42/ EC or is marketed as PPE per 89/686/EEC documentation required to show how Essential Requirements of these directive are met | Description of test methodology and test environment/configuration  Review Minutes  Especially for SW:  Unit tests, system tests, integration tests  Verification of SOUPs  Performance tests, stress tests, cybersecurity tests  Reports and summaries of the results.  Note: MDCG 2020-13 can be used as guidance to understand how the notified bodies are required to assess manufacturer’s clinical evidence. |  |  |
| Annex III | Technical Documentation on Post-Market Surveillance | Includes PMS Plan, PMS Report and PSUR (MDCG 2022-21)  Minimum requirements for PMS Plan sources of information  Specific guidance on how to evaluate PMS  data  Requirement (via Article 83) to update clinical evaluation, SSCP, design and manufacturing information and information for use on the basis of PMS output  Follows guidance of the ISO TR 20416. | Methods for Active and Reactive PMS. PMS report device-specific including per year, sales by geographical areas & complaints/nonconforming product. Evaluation of complaints/trends. Review of information from other sources e.g. literature, databases, regulatory body assessments, data from service reports/repairs. Summary of actions taken – Vigilance reports, FSCA, corrective actions, risk management documents updated, review status of ongoing requirement for PMCF. |  |  |

**Notes and instructions:**

1. The space on page 1 may be changed to suit your approval and issue requirement.
2. The first column lists the Technical Documentation topic
3. In the second column please indicate whether the GSPR is applicable or not applicable for your product.
4. If the GSPR is deemed N/A then a written justification must be included in the fourth column.
5. In the third column enter the reference number and version of any standard/ specifications that has been used.
6. In the fourth column describe the documents, procedures or reports that are used as evidence of satisfying the GSPR. Also indicate at which location the documents, procedures or reports are being kept if this useful.
7. A List of Harmonised Standards with current valid versions can be found on the European Commission website. In those areas where there are no harmonized standards for MDR, the harmonized standards for MDD can be used as a guideline. The most recent revision of the international standards represent the current best practice.
8. Use of standards is preferred, but not compulsory. If other means are used, it should be expected that the notified body must use substantial additional time to verify and and validate the results with regard to compliance.

For the contents of the documentation it is recommended to use the [Team-NB Position Paper BPG Technical Doc EU-MDR 2017-745 V1](https://www.team-nb.org/wp-content/uploads/2022/10/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V1-20221005.pdf) as guidance.