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| **Company name and Address** | | |
| **Device Identification and Technical File ID** (repeat in page headers)  [Title] | | |
| **Description of the Device** | | |
| **Range of Devices (models) covered by checklist** | | |
| **Classification + Rule** | | |
| **NBOG MD Code and/or GMDN Number** | | |
| **Checklist ID and Revision No** (repeat in page headers)  [Subject] | | |
| **Prepared by** | **Approved by** | **Date checklist approved** (repeat in page headers)**:**  [Publish Date]  **2019-11-21** |

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| **I** | **PART A – CLINICAL EVALUATION** |  |  |  |  |
| 1 | To plan, continuously conduct and document a clinical evaluation, manufacturers shall:  (a) establish and update a clinical evaluation plan, which shall include at least: |  |  |  |  |
| * - an identification of the general safety and performance requirements that require support from relevant clinical data; |  |  |  |  |
| * a specification of the intended purpose of the device; |  |  |  |  |
|  | * a clear specification of intended target groups with clear indications and contra-indications; |  |  |  |  |
|  | * a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters; |  |  |  |  |
|  | * a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects; |  |  |  |  |
|  | * an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device; |  |  |  |  |
|  | * an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non- viable animal or human tissues, are to be addressed; and |  |  |  |  |
|  | * a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria; |  |  |  |  |
|  | (b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review; |  |  |  |  |
|  | (c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device; |  |  |  |  |
|  | (d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and |  |  |  |  |
|  | (e) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits. |  |  |  |  |
| 2 | The clinical evaluation shall be thorough and objective, and take into account both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's claims in respect of the device. |  |  |  |  |
| 3 | A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence: |  |  |  |  |
|  | * Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements; |  |  |  |  |
|  | * Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables; |  |  |  |  |
|  | * Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose. |  |  |  |  |
|  | The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence. |  |  |  |  |
| 4 | The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device. |  |  |  |  |
|  | The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation for the device in question. |  |  |  |  |
|  | Both favourable and unfavourable data considered in the clinical evaluation shall be included in the technical documentation. |  |  |  |  |
| **II** | **POST-MARKET CLINICAL FOLLOW-UP** |  |  |  |  |
| 5 | PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence. |  |  |  |  |
| 6 | PMCF shall be performed pursuant to a documented method laid down in a PMCF plan. |  |  |  |  |
| 6.1 | The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of: |  |  |  |  |
|  | (a) confirming the safety and performance of the device throughout its expected lifetime, |  |  |  |  |
|  | (b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, |  |  |  |  |
|  | (c) identifying and analysing emergent risks on the basis of factual evidence, |  |  |  |  |
|  | (d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and |  |  |  |  |
|  | (e) identifying possible systematic missuse or off-label use of the device, with a view to verifying that the intended purpose is correct. |  |  |  |  |
| 6.2 | The PMCF plan shall include at least: |  |  |  |  |
|  | (a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data; |  |  |  |  |
|  | (b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies; |  |  |  |  |
|  | (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b); |  |  |  |  |
|  | d) a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I; |  |  |  |  |
|  | (e) the specific objectives to be addressed by the PMCF; |  |  |  |  |
|  | (f) an evaluation of the clinical data relating to equivalent or similar devices; |  |  |  |  |
|  | (g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and |  |  |  |  |
|  | (h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer. |  |  |  |  |
| 7 | The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation. |  |  |  |  |
| 8 | The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them. |  |  |  |  |

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|  | **REQUIREMENTS ORIGINATING FROM MEDDEV 2.7/1 R4** |  |  |  |  |
| A9 | Clinical evaluation report - proposed table of contents, examples of  contents |  |  |  |  |
|  | 1. Summary:   Executive summary, summary for external purposes.  This section should summarise the determination of the benefit/risk profile in the intended target groups and medical indications, and the demonstration of acceptability of that profile based on the state of the art in the medical fields concerned. |  |  |  |  |
|  | 1. Scope of the clinical evaluation   See Section 7 and Appendix A3 (of MDR 2.7/1 R4).  Identification of devices covered by this clinical evaluation report, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development. Name and address of the manufacturer.  ~~Whether this clinical evaluation is submitted to the AIMDD as amended by directive 2007/47/EC, or to the MDD as amended by directive 2007/47/EC.~~  Concise physical and chemical description, including materials. Whether the device incorporated medicinal substances (already on the market or new), tissues, or blood products. Mechanical and physicochemical characteristics; others (such as sterile vs. nonsterile,  radioactivity etc.); picture or drawing of the device.  Technologies used, whether the device is based on a new  technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. Description of innovative aspects of the device.  Device group the device belongs to. How the device achieves its intended purpose. Positioning in relation to available treatment/management/ diagnostic options.  Exact description of the intended purpose as described in the device's IFU, with exact medical indications (if applicable) and contraindications; claims made in available promotional materials.  Name of disease or condition, clinical form, stage, severity,  symptoms or aspects to be treated/ managed/ diagnosed, target patient population, target user group. Intended application of the device, single use/reusable, invasive/non invasive, implantable, duration of use or contact with the body, maximum number of repeat applications. Identification of organs, tissues or body fluids  contacted by the device. Precautions.  Claims on clinical performance and clinical safety foreseen by the manufacturer.  Whether the device is already CE marked, whether it is on the market, since when, in what regions, history of the device, including date of past modifications with reasons and description, sales volumes.  Changes since the last report, whether the device has been modified, identification of new products, models, sizes, software, accessories, new intended purposes, new claims, new events related to the device with an impact on clinical evaluation. Identification of the sections of the clinical evaluation report that are concerned with the new information and have been modified.  Other aspects. |  |  |  |  |
|  | 1. Clinical background, current knowledge, state of the art   See Sections 8-10 and Appendices A4-A5 (of MDR 2.7/1 R4).  Identification of medical fields concerned/ relevant medical  conditions.  Brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/ the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. Appraisal criteria used.  Applicable standards and guidance documents.  Description, natural course and consequences of the medical conditions concerned. Whether there are different clinical forms, stages and severities of the conditions. Frequency in the general population, by age group, gender, ethnicity, familiar predispositions, genetic aspects.  Description of available therapeutic/ management/ diagnostic options, historical context and developments, summary of advantages and disadvantages of the different options, benefit/ risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions and in relation to different target populations. Description of the benefits and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects and other risks (including the nature, severity, probability and duration of acceptable harm).  Hazards due to substances and technologies that could be  relevant to the device under evaluation. The mechanisms of harm, clinical aspects of minimisation and management of side effects and other risks.  Types of users. Diverging opinions of professionals as to the use of the different medical options. Unmet medical needs. |  |  |  |  |
|  | 1. Device under evaluation |  |  |  |  |
|  | * 1. Type of evaluation   Whether the clinical evaluation is based on  - scientific literature currently available, and/or  - clinical investigations made  or  - whether demonstration of conformity with essential requirements based on clinical data is not deemed appropriate.  If clinical data is not deemed appropriate, include considerations according to Section 10.3. |  |  |  |  |
|  | * 1. Demonstration of equivalence (only when equivalence is claimed)   See Appendix A1 (of MEDDEV 2.7/1 Rev.4).  Identification of the equivalent device and its manufacturer. Exact name, models, sizes, software versions, accessories, etc. Name of the manufacturer. Relationship to the device under evaluation (predecessor/ successor, others). Regulatory status. If the device is not CE-marked, justification for the use of the data.  Comparison of clinical, biological and technical characteristics (see Appendix A1 for details). Justification of equivalence, description of relevant clinical, biological and technical characteristics that affect clinical properties of the device, differences between the intended purpose of the device under evaluation and the equivalent device (indications, contraindications, precautions, target patient groups, target users, mode of application, duration of use/ number of re-applications, others), type of device-body interaction. Choice, justification and validity of parameters and models for non-clinical determination of characteristics.  Identification of pre-clinical studies carried out and literature used, concise summaries of studies and literature (methods, results, conclusions of the authors), evaluation of the methodological quality of the study or document, the scientific validity of the information.  Comparative tabulations for the device under evaluation versus the equivalent device showing parameters relevant to the evaluation of the three characteristics. Comparative drawings or pictures of the device and the equivalent device showing the elements in contact with the body.  Identification of differences, evaluation if differences are expected or not to influence the clinical performance and clinical safety of the device, reasons for assumptions made.  Conclusions concerning equivalence. Whether the comparison carried out covers all products/ models/ sizes/ settings/accessories and the entire intended purpose of the device under evaluation, or only certain products/ models/ sizes/ settings/accessories, or selected aspects of the intended purpose, which ones.  Conclusions whether equivalence is demonstrated or not; if it is demonstrated, confirmation that the differences are not expected to affect the clinical performance and clinical safety of the device under evaluation; description of any limitations and gaps. |  |  |  |  |
|  | * 1. Clinical data generated and held by the manufacturer   See Section 8.1.  Identification of clinical data generated and held by the manufacturer. |  |  |  |  |
|  | * 1. Clinical data from literature   See Section 8.2 and Appendices A4-A5 (of MEDDEV 2.7/1 Rev.4).  Brief summary and justification of the literature search strategy applied for retrieval of clinical data, including objectives, sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent. |  |  |  |  |
|  | * 1. Summary and appraisal of clinical data   See Section 9 and Appendix A6 (of MEDDEV 2.7/1 Rev.4).  - Feasibility Studies  - Pivotal clinical investigations  - PMCF Studies  - Other use data  Summaries of clinical data generated and held by the  manufacturer and of scientific literature found to be pertinent. Including brief summary of the studies or references (methods, results, conclusion of the authors), evaluation of their methodological quality, scientific validity of contents, relevance to the clinical evaluation, weighting attributed to the data, contents used (performance data, safety data, both) reasons for rejecting a study or document, reasons for rejecting some of its contents. |  |  |  |  |
|  | * 1. Analysis of the clinical data |  |  |  |  |
|  | * + 1. Requirement on safety ~~(MDD ER1 / AIMDD ER1)~~   See Section 10 and Appendix A7.1 (of MEDDEV 2.7/1 Rev.4).  Summary of conformity assessment with requirement on ~~safety (MDD ER1 / AIMDD ER1).~~ General Safety and Performance Requirements of Annex I of MDR.  Analysis whether there are special design features that pose special safety concerns (e.g. presence of medicinal, human or animal components, presence of nanomaterials) that where identified in the device risk management documentation and that required evaluation from a clinical perspective, and whether these have been adequately addressed.  Whether the risks identified in the risk management documentation and literature have been adequately addressed.  Whether all the hazards and other clinically relevant information (e.g. clinical precautions for reduction of risks, clinical management of risks) have been identified appropriately.  Whether the safety characteristics and intended purpose of the device requires training of the end-user or other precautions, if users foreseen are adequate, if training requirements and other precautions are described in the IFU.  Whether there is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the manufacturer, and the risk management documentation for the device |  |  |  |  |
|  | * + 1. Requirement on acceptable benefit/risk profile ~~(MDD ER1 /AIMDD ER1)~~ (General Safety and Performance Requirements of Annex I of MDR)   See Section 10 and Appendix A7.2 (of MEDDEV 2.7/1 R4).  Summary of conformity assessment with requirement on acceptable benefit/risk ~~profile (MDD ER1 / AIMDD ER1)~~ General Safety and Performance Requirements of Annex I of MDR.  Summary of the total experience with the device, including estimated numbers and characteristics of patients exposed to the device in clinical investigations, PMCF, from other user experience, and in the market; duration of follow-up. Nature, extent/severity, probability/frequency, duration of benefits to the patients and of undesirable side-effects and other risks. For each aspect of the intended purpose, whether the benefit/risk profile including its uncertainties or unanswered questions is compatible with a high level of protection of health and safety, corresponding justifications. |  |  |  |  |
|  | * + 1. Requirement on performance ~~(MDD ER3 /AIMDD ER2)~~ General Safety and Performance Requirements of Annex I of MDR   See Section 10 and Appendix A7.3 (of MEDDEV 2.7/1 R4) .  Summary of conformity assessment with requirement on performance ~~(MDD ER3 / AIMDD ER2)~~ General Safety and Performance Requirements of Annex I of MDR. Description of clinical performance. For each intended performance, extent to which evaluation of benefits is possible based on available data, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions. whether available data  allows adequate evaluation of performance, limitations of the data, gaps, uncertainties or unanswered questions. Whether there is sufficient clinical evidence for every intended performance. |  |  |  |  |
|  | * + 1. Requirement on acceptability of side-effects ~~(MDD ER6 /AIMDD ER5)~~   See Section 10 and Appendix A7.4 (of MEDDEV 2.7/1 R4) .  Summary of conformity assessment with requirement on acceptability of undesirable side-effects ~~(MDD ER6 / AIMDD ER5)~~.  Whether the data available is of sufficient amount and quality for the detection of undesirable side-effects and their frequency, limitations of the data, description of gaps, uncertainties or unanswered questions, and assumptions.  Whether the undesirable side-effects are acceptable and corresponding justifications. |  |  |  |  |
|  | 1. Conclusions   See Section 11.  Clear statement concerning compliance to ~~Essential requirements~~ General Safety and Performance Requirements of Annex I of MDR.  Acceptability of the benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives.  Adequacy of the information materials supplied by the  manufacturer, whether the intended purpose and risk reduction measures are adequate; discrepancies.  Suitability of the device, including its IFU, for the intended users and usability aspects; discrepancies.  Adequacy of claims foreseen by the manufacturer; discrepancies.  If there is consistency between the clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation; discrepancies.  Whether there is consistency between these documents and the current knowledge/ the state of the art; discrepancies.  Description of residual risks and uncertainties or unanswered questions, whether these are acceptable for CE-marking, how these should be followed during PMS (uncertainties regarding medium- and long term performance, safety under wide-spread use, residual risks such as undesirable side-effects and complications occurring at rates below detection possibilities of currently available clinical data, others).  Whether these are already being addressed in ongoing PMS activities, e.g. in currently ongoing PMCF studies.  Whether new or additional PMS activities,  including PMCF studies, should be foreseen. |  |  |  |  |
|  | 1. Date of the next clinical evaluation   See Section 6.2.3.  Suggested date, justification of the date. |  |  |  |  |
|  | 1. Dates and signatures   See Section 11.  Date of the clinical evaluation report.  Statement that the evaluators agree with the contents of the report. Dates, names and signatures of the evaluators.  Final release by the manufacturer. Date, name and signature. |  |  |  |  |
|  | 1. Qualification of the responsible evaluators   See Section 6.4. |  |  |  |  |
|  | 1. References   See Section 11. |  |  |  |  |
| A10 | **Checklist for the release of the clinical evaluation report** |  |  |  |  |
|  | Can the report be read and understood by a third party, does it provide sufficient detail for understanding the data that are available, all assumptions made and all conclusions reached? |  |  |  |  |
|  | If clinical data have been generated and are held by the manufacturer, are all data mentioned and adequately summarised in the report? |  |  |  |  |
|  | If equivalence is claimed,  - is demonstration of equivalence included in the report?  - does the report disclose all the differences between the device under evaluation and the equivalent device?  - does it explain why the differences are not expected to affect the clinical performance and clinical safety of the device? |  |  |  |  |
|  | If the product is already in the market in Europe or elsewhere, has the latest PMS/ PMCF data been taken into consideration and has it been summarised and referenced in the report? |  |  |  |  |
|  | In respect to current knowledge/ the state of the art,  - has the report been updated?  - is current knowledge/ the state of the art summarised in the report and is it adequately substantiated by literature?  - does the content of the report fully correspond to current knowledge/ the state of the art?  - does the report explain why the benefit/risk profile and the undesirable side-effects are acceptable in relation to current knowledge/ the state of the art? |  |  |  |  |
|  | If the report covers several models/ sizes/ settings and/or different clinical situations, is there sufficient clinical evidence and are the report’s conclusions correct for  - all the devices?  - all its sizes, models and settings? (including the smallest/ largest size, highest/ lowest dose, etc.)  - every medical indication? (as described in the IFU/ not excluded with contraindications in the IFU)  - the entire target population? (from pre term infants to old age, for males and females, etc., if not restricted in the IFU)  - every form, stage and severity of the medical condition, as applicable? (including the most severe/ most benign forms, acute/ chronic stage, if not excluded in the IFU)  - all intended users? (including lay persons, if not excluded in the IFU, and any unusual user group)  - the whole duration of product use, including the maximal number of repeated exposure? (as allowed by the IFU)  - if there are any discrepancies as to the above, are they identified in the report’s conclusions? |  |  |  |  |
|  | Is conformity to each of the relevant General Safety and Performance Requirements of Annex I of MDR ~~Essential requirements (AIMDD ER1,2,5 / MDD ER1,3,6 )~~ clearly stated and are all discrepancies identified in the report’s conclusions? |  |  |  |  |
|  | Do the information materials supplied by the manufacturer correspond with the contents of the report and are all discrepancies identified in the report’s conclusions? |  |  |  |  |
|  | Do the report’s conclusions identify all residual risks and uncertainties or unanswered questions that should be addressed with PMS/ PMCF studies? |  |  |  |  |
|  | Is the report dated? |  |  |  |  |
|  | Is the qualification of the evaluators included in the report and correct? |  |  |  |  |
|  | Does the manufacturer hold a CV and declaration of interests of each of the evaluators and are these up-to-date? |  |  |  |  |
| **A11** | **Information on declarations of interests** |  |  |  |  |
|  | Declarations of interests of the evaluators should be held by the manufacturer and cover relevant financial interests outside the current work as an evaluator.  Declarations of interests should contain statements that clarify the extent of the declaration.  For example:  - the time span included (e.g. grants, sources of revenue or benefits paid or promised to be paid over the 36 months prior to the evaluation)  - whether financial interests of family members are included or not (namely spouse or partner living in the same residence as the evaluator, children and adults for whom the evaluators is legally responsible) |  |  |  |  |
|  | Typical contents: |  |  |  |  |
|  | * employment by the manufacturer |  |  |  |  |
|  | * participation as an investigator in clinical studies of the device, or in pre-clinical testing of the device |  |  |  |  |
|  | * ownership/ shareholding possibly affected by the outcome of the evaluation |  |  |  |  |
|  | * grants sponsored by the manufacturer |  |  |  |  |
|  | * benefits such as travelling or hospitality (if beyond what is reasonably necessary for the work as an employee or external evaluator) |  |  |  |  |
|  | * interests in connection with the manufacturing of the device or its constituents |  |  |  |  |
|  | * interests in connection with intellectual property, such as patents, copyrights and royalties (whether pending, issued or licensed) possibly affected by the outcome of the evaluation |  |  |  |  |
|  | * other interests or sources of revenues possibly affected by the result of the evaluation |  |  |  |  |

**Notes and instructions:**

1. The space on page 1 may be changed to suit your approval and issue requirement.
2. New or revised Essential Requirements as amended by Directive 2007/47/EC are shown in bold to aid the implementation phase, but may be changed to normal font when appropriate.
3. The second column lists the requirements of Regulation (EU) 2017/745
4. In the third column indicate whether the requirement is applicable or not applicable for your product.
5. If the requirement is deemed N/A then a written justification must be included in the fourth column.
6. In the fourth column describe the documents, procedures or reports that are used as evidence of satisfying the requirement. Also indicate at which location the documents, procedures or reports are being kept if this useful.

The text in blue font is intended as guidance and can be removed from the final checklist.

The text in green font depicts difference from MDD to MDR in MEDDEV 2.7/1 R4.