**Overview of submitted documents for MDR applications**

An application for clinical investigation of a medical device shall contain the documentation listed in this document. Please fill in the form below to provide an overview of documents included in the application.

* Documents shall preferably be numbered according to the list below.
* More than one document can be entered per section, if needed.
* When preparing the application, please consult *ISO 14155:2020 Clinical investigation of medical devices – Good clinical practice* for guidance.
* Templates are provided on NOMA’s website.

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| **SECTION 1. MANDATORY DOCUMENTS** | | | |
| **#** | **Required documentation** | **Name/ID of submitted document(s)** | **Included?** |
| 0 | **Overview of submitted documents** (this document) | fill in | ☐ |
| 1 | **Cover letter**  Please use the template provided by NOMA | fill in | ☐ |
| 2 | **Application/Notification form, with relevant appendices if needed**  Please use the template(s) provided by Medical Device Coordination Group (MDCG). | fill in | ☐ |
| 3 | **Investigator's Brochure (IB)**  IB shall fulfill the requirements of MDR, Annex XV, chapter II, 2.1 - 2.8, and preferably follow its layout with regards to subtitles. | fill in | ☐ |
| 4 | **Clinical Investigation Plan (CIP)**  CIP shall fulfill the requirements of MDR, Annex XV, chapter II, 3.1 - 3.19, and preferably follow its layout with regards to subtitles.  **The CIP should also contain synopsis for the clinical investigation in both Norwegian and English language**  Cf. MDR, Annex XV, chapter II, 3.1.5. This should be included in the CIP or as a separate document. If the synopsis is included in a separate document, a reference should be included in the CIP. | fill in | ☐ |
| 5 | **Signed statement that the device conforms to regulatory requirements: Statement of conformity**  Cf. MDR, Annex XV, chapter II, 4.1, for content of the statement or use the template provided by NOMA. | fill in | ☐ |
| 6 | **MDR Annex XV check list for IB and CIP**  Please use the template provided by NOMA. | fill in | ☐ |
| 7 | **GSPR and standards check list**  Please use the template provided by Medical Device Coordination Group (MDCG). | fill in | ☐ |
| 8 | **Proof of insurance cover of subjects**  A copy of the insurance policy or written confirmation from The Norwegian System of Patient Injury Compensation (NPE). | fill in | ☐ |
| 9 | **Documents to be used to obtain informed consent**  Including the patient information sheet and the informed consent document. Templates are found on the Regional Ethics Committees [web site](https://rekportalen.no/#omrek/REK_KULMU). | fill in | ☐ |
| 10 | **Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data**  Cf. MDR, Annex XV, chapter II, 4.5. You may consult the [The Code of Conduct](https://www.ehelse.no/normen) for information on security and data protection in healthcare, and the web site of the [The Norwegian Data Protection Authority](https://www.datatilsynet.no/en/) for information on GDPR. | fill in | ☐ |
| 11 | **Confirmation on the suitability**  **of the investigational site(s)**  The confirmation should be signed by the person in charge at the investigational site. | fill in | ☐ |
| 12 | **Confirmation on the suitability of investigation site team**  CV for principal investigator(s) (PI) | fill in | ☐ |
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| **SECTION 2. DOCUMENTS THAT ARE MANDATORY IF APPLICABLE TO THE CLINICAL INVESTIGATION** | | | |
| **#** | **Documents** | **Name/ID of document(s)** | **Please indicate** |
| 13 | **Opinion from an Expert panel**  If an expert panel has been consulted according to MDR Article 61.2, the opinion from the expert panel shall be included. | fill in | Included  N/A |
| 14 | **Documentation according to MDR, Annex XV, chapter II, 2.6**  Shall be submitted if the investigational device:   * incorporates a medicinal substance, including a human blood or plasma derivative, or * is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives | fill in | Included  N/A |

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| **SECTION 3. OTHER DOCUMENTS (if relevant)** | | |
| **#** | **Description of the content of the document(s)** | **Document ID/name** |
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