Overview of submitted documents for IVDR applications

An application for performance study of an in vitro diagnostic 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 20916:2019 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice.
* Templates are provided on NOMA’s website.

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| **SECTION 1: MANDATORY DOCUMENTS** |
| **#** | **Required documentation** | **Document name and version/date [DD-MM-YY] at time of application to NOMA** |
| 0 | **Overview of submitted documents** (this document) | fill in |
| 1 | **Cover letter** Please refer to our website for information on what should be included in the cover letter. | 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 fulfil the requirements of IVDR, Annex XIV, chapter I, 2.1 - 2.8 and preferably follow its layout with regards to subtitles. | fill in |
| 4 | **Clinical Performance Study Plan (CPSP)**CPSP shall fulfil the requirements of IVDR, Annex XIII, Part A, Section 2.3.2 and preferably follow its layout with regards to subtitles. | fill in |
| 5 | **Signed statement that the device conforms to regulatory requirements: Statement of conformity**Cf. IVDR, Annex XIV, chapter I, 4.1 for content of the statement or use the template provided by NOMA. | fill in  |
| 6 | **IVDR Annex XIV check list for CPSP and IB**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 can be found on the [Norwegian Ethics Committees for Clinical Trials on Medicinal Products and Medical Devices (REK KULMU)s website](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. IVDR, Annex XIV, chapter I, 4.5. You may consult [The Code of Conduct for information on security and data protection in the healthcare and care services](https://www.ehelse.no/normen) and the web site of [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) at each site. | fill in |

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| **SECTION 2: OTHER DOCUMENTS (if relevant)** |
| **#** | **Description of the content of the document(s)** | **Document name and version/date [DD-MM-YY] at time of application to NOMA** |
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