Application for a Performance Study

Validation of this application will be completed and the review will commence only once all the relevant accompanying documentation is submitted. If completed documentation is not received within the timeframe specified in a notification of an incomplete application from the HPRA, the application will be deemed lapsed.

Applications will be accepted via the Common European Submission Portal (CESP), unless previously agreed with the HPRA. Please submit the completed form and all accompanying documents at <https://cespportal.hma.eu>. Following submission of documents via this portal please send an email to devices@hpra.ie to advise that a new performance study (PS) application has been submitted.

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| SECTION A: Administrative Information |
| 1 | Is this a first submission, resubmission or substantial modification?[ ]  First submission[ ]  Resubmission[ ]  Substantial modification |
| 2 | If resubmission or substantial modification, state previous submission date and HPRA reference number.Date      Reference no.       |
| 3 | SIN/EUDAMED number:       |
| 4 | Enter the contact details of the sponsor who is responsible for this application.Name      Address      Telephone      Email       |
| 5 | Where the sponsor referred to in point 4 above is not established in the Union, enter the contact details of a legal representative who is established in the Union (c.f. Art 58(4) IVDR 2017/746).Name      Address      Telephone      Email       |
| 6 | Investigator responsible for the conduct of the performance study in Ireland.*If more than two investigators are involved, please attach these details as an appendix, including a brief description of the role for each member of the investigator’s team who will be directly involved in the conduct of the performance study.*(i) Name      Qualification      Address      Telephone      Email      (ii) Name      Qualification      Address      Telephone      Email       |
| 7 | Please list the performance study sites in Ireland.*If more than two sites, please attach details in an appendix.**Irish site 1* Name      Address      *Irish site 2* Name      Address       |
| 8 | Do the investigators together with the investigation sites listed above have the capability to conduct the performance study in accordance with the proposed performance study plan?[ ]  Yes[ ]  No  |
| 9 | Is this part of a multi-site performance study outside Ireland? If so, enter details of other sites located outside of Ireland. *If more than two sites, please attach details in an appendix.**Non-Irish site 1* Name      Address      *Non-Irish site 2* Name      Address       |
| 10 | Principal investigator appointed to coordinate the work in a multi-site study:Name      Qualification      Address      Telephone      Email       |
| 11 | Manufacturer's name and address including site where the manufacture of the device is taking place:Name      Address      Telephone      Email       |
| 12 | If the manufacturer is not based in a European Union Member State, name, address and contact details of the authorised representative:Name      Address      Telephone      Email       |
| 13 | Enter the details of the notified body/bodies who approved the quality system at the site referred to in point 11 above (if applicable).*Notified Body 1*Name      Address      Identification no.      *Notified Body 2*Name      Address      Identification no.       |
| 14 | Is this application submitted in parallel with an application for a clinical trial in accordance with EU Regulation 536/2014? If so, please provide reference number. [ ]  Yes[ ]  NoClinical trial reference no.       |
| 15 | Please confirm that an application has been submitted to the National Research and Ethics Committee- Medical Devices (NREC-MD) and if so, indicate the date on which this application was made.[ ]  Yes[ ]  NoDate:       |
| 16 | Payment details (please include documentary confirmation of payment with your application, where applicable):[ ]  Cheque[ ]  Bank transfer[ ]  Bank draft[ ]  Credit on account |

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| SECTION B: device information |
| 1 | Name of device:       |
| 2 | Nomenclature or generic name of device:       |
| 3 | Device description:       |
| 4 | Does the device incorporate tissue, cells or substances of human, animal or microbial origin? [ ]  Yes[ ]  No |
| 5 | Proposed device classification:[ ]  Class A[ ]  Class B[ ]  Class C[ ]  Class D |
| 6 | Will a comparator device be used during this performance study?[ ]  Yes[ ]  NoIf yes, please provide details of the comparator device, including its classification and any information necessary for its identification. |

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| SECTION C: Performance Study information |
| 1 | Full title of performance study:  |
| 2 | Short title of performance study (if applicable):  |
| 3 | Title for lay persons:  |
| 4 | Is surgically invasive sample-taking done only for the purpose of the performance study? [ ]  Yes[ ]  NoIf yes, please confirm if the specimen collection represent a major clinical risk to the subject of the study; please provide justification for your response.  |
| 5 | Summary of the performance study plan (PSP), including:* the objectives of the performance study,
* the number and gender of subjects,
* criteria for subject selection,
* whether any subjects are under 18 years of age,
* design of the performance study, and
* planned dates of commencement and completion of the performance study.

*Note: Where the summary is included as an appendix please reference the document.*  |
| 6 | PSP code:  |
| 7 | Has this CPS been the subject of a scientific review/opinion from a regulatory authority?[ ]  Yes[ ]  NoIf yes, please provide details.  |
| 8 | In the case of a resubmission or a substantial modification, have any changes been made to address the conclusions of previous competent authority or Ethics Committee reviews?[ ]  Yes[ ]  No(If yes, please ensure that all changes are identified and a rationale for those changes is provided in accompanying documentation.) |

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| **SECTION D: Documentation to be attached** |
| Annexes XIII and XIV of the IVDR 2017/746 set out the full description of documentation required for a performance study. Additional requests for documentation and information may be made following submission of the application. Please ensure that all questions are answered. The content and structure of documents submitted should be in line with relevant regulatory requirements and associated standards. Please provide section/page references for all items below including a reference to the source document if the information is not within the PSP.  |
| 1. **Performance Study Plan (PSP)** (*which sets out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the performance study.)*

 Version number      Date       |
| Reference |
| 1. Identification and contact details of the sponsor and where applicable the identification and contact details of the legal representative.
 |       |
| 1. Identification of the investigator or investigators, namely principal, coordinating or other investigator; qualifications; contact details, and investigation site or sites, such as number, qualification, contact details and, in the case of devices for self-testing, the location and number of lay persons involved.
 |       |
| 1. The starting date and scheduled duration for the performance study.
 |       |
| 1. Identification and description of the device, its intended purpose, the analyte(s) or marker(s), the metrological traceability and the manufacturer.
 |       |
| 1. Information about the type and specimens under investigation.
 |       |
| 1. Overall synopsis of the performance study, its design, objectives and hypothesis, reference to the current state of the art in diagnosis and/or medicine.
 |       |
| 1. Expected risks and benefits of the device and the study in context of the state of the art in clinical practice and with exception to studies using left over samples, the medical procedures involved and patient management.
 |       |
| 1. Instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other device, medicinal product or article and specifications on any comparator or comparative method used as reference.
 |       |
| 1. Description and justification of design with evidence of its scientific robustness and validity, including statistical design, and details of measures taken to minimise bias and management of potential confounding factors.
 |       |
| 1. Details of the analytical performance in accordance with point (a) of section 9.1 of Chapter I of Annex I with justification for any omission.
 |       |
| 1. Parameters of performance in accordance with point (b) of section 9.1 of Annex I to be determined, with justification for any omission; and with the exception of studies using left over samples, the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions.
 |       |
| 1. Information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity of target population and, if applicable, information on vulnerable subjects involved, such as children, pregnant women, immuno-compromised or elderly subjects.
 |       |
| 1. Information on use of data of left over specimens banks, genetic or tissue banks, patient or disease registries, etc., with description of reliability and representativity and statistical analysis approach, assurance of relevant method for determining the true clinical status of patient specimens.
 |       |
| 1. Description of monitoring plan.
 |       |
| 1. Description of data management plan.
 |       |
| 1. Description of decision algorithms.
 |       |
| 1. Policy regarding and amendment or deviations to the PSP, with a clear prohibition of use of waivers from the PSP.
 |       |
| 1. Accountability regarding the device, in particular control of access to the device, follow up in relation to the device used in the performance study and the return of unused, expired or malfunctioning devices.
 |       |
| 1. Statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of performance studies as well as with the applicable regulatory requirements.
 |       |
| 1. Description of informed consent process, including copy of patient information leaflet and consent form.
 |       |
| 1. Procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting.
 |       |
| 1. Criteria and procedures for suspension or early termination of the performance study.
 |       |
| 1. Details of and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up.
 |       |
| 1. Procedures for communication of test results outside the study and to the performance study subjects.
 |       |
| 1. Policy as regards the establishment of the performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in section 2.2.
 |       |
| 1. List technical and functional features of the device indicating those that are covered by the performance study.
 |       |
| 1. Bibliography
 |       |
| 1. **Investigator’s Brochure (IB)**
 | References |
| 1. An identification and description of the device including information on: the intended purpose, the risk classification and applicable classification rule (Annex VIII), design and manufacturing of the device and reference to previous and similar generations of the device. Data allowing identification of device: (i) generic name, (ii) model name, (iii) model number.
 |       |
| 1. Instructions for installation, maintenance, hygiene and use including storage and handling requirements, and relevant training required. Also, to the extent available, information to be placed on label and instructions for use to be provided when device is placed on the market.
 |       |
| 1. Analytical performance
 |       |
| 1. Existing clinical data:
* from relevant peer-reviewed scientific literature and available consensus expert opinions or positions from relevant professional associations relating to the safety, performance, clinical benefits to patients, design characteristics, scientific validity, clinical performance and intended purpose of the device and/or of equivalent or similar devices; and,
* other relevant clinical data available relating to the safety, scientific validity, clinical performance, clinical benefits to patients, design characteristics and intended purpose of similar devices, including details of their similarities to and differences from the device in question.
 |       |
| 1. Summary of risk-benefit analysis and risk management, including information on known or foreseeable risks, any undesirable effects, contraindications and warnings.
 |       |
| 1. In the case of devices that include tissues, cells and substances of human, animal or microbial origins, detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to those tissues, cells and substances.
 |       |
| 1. A list detailing the relevant GSPRs, including the standards and common specifications applied (specify whether applied in whole or in part). Also a description of the solutions for fulfilling the relevant GSPRs, insofar as those standards and CS have not or have only been partly fulfilled, or are lacking.
 |       |
| 1. Detailed description of the clinical procedures and diagnostic tests used in the course of the performance study and in particular information on any deviation from normal clinical practice.
 |       |
| 1. Confirm that procedures are in place to ensure the IB is kept up to date and the investigator is informed of any/all updates.
 |       |
| **3 Additional information** | References |
| 1. Detailed description of the clinical procedures and diagnostic tests used during the study and information on any deviation from normal clinical practice.
 |       |
| 1. Details of new or previously untested features of the device including, where applicable, functions and principles of operation.
 |       |
| 1. Description and details of material and/or chemical composition of device components.
 |       |
| 1. Where applicable, results of mechanical, thermal, electrical and/or radiation safety testing.
 |       |
| 1. Where applicable, software verification and validation testing and results.
 |       |
| **4 Documents and statements** | References |
| 4.1 A signed statement that the device meets the general safety and performance requirements set out in Annex I apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons. |       |
| * 1. A copy of the opinion of the National Office for Research Ethics Committee (NREC).
 |       |
| * 1. Documents used to obtain informed consent.
 |       |
| 4.4 Confirmation of insurance of subjects. |       |
| * 1. Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data.
 |       |

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| SECTION E: Declaration |

Signed on behalf of **<company name>**.

I, *(please print full name in block capital letters)* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. As the natural or legal person responsible for the manufacture of the device, certify that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.
2. Certify that the information and documentation submitted with this application is correct in detail and all the information requested has been supplied. Any further information requested by the competent authority will be submitted on request.
3. Agree to report without delay to all Member States in which a performance study is being conducted any serious adverse events or any other events as referred to in Article 76 (2) of Regulation (EU) 2017/746.
4. Undertake to keep available for the competent authority for a period of 10 years after the end of the performance study, or, where the device is subsequently placed on the market, from the time the device was last placed on the market, all the documentation referred to in Annex XIV of Regulation (EU) 2017/746.
5. Certify that the sponsor consents to allow the final letter detailing the outcome of the HPRA review to be copied to the Irish based investigators and the relevant Ethics Committee(s).
6. Certify that the sponsor consents to the HPRA contacting the relevant Ethics Committee(s) during the course of the review if required.
7. Certify that the sponsor consents to the HPRA utilising external experts, when necessary, during the assessment of this application. (Experts used will be subject to the HPRA’s procedures for protection of confidentiality and impartiality).

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Position:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Company name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please submit the completed form and all accompanying documents via the Common European Submission Portal at <https://cespportal.hma.eu/>.