Notification of a Performance Study of a CE Marked IVD (Article 70 IVDR)

Please note that only certain performance studies of CE marked medical devices need to be notified to the HPRA under Article 70 of the IVDR.

This notification form only applies to performance studies where the proposed use is consistent with the intended purpose of the device. Where a CE marked device is proposed to be used outside the scope of its intended purpose, an application to undertake a performance study of the IVDR should be made instead. Please refer to the HPRA [Guide to Performance Studies Conducted in Ireland](https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/guide-to-performance-studies-conducted-in-ireland.pdf?sfvrsn=5) for further details.

Notifications will only be accepted via CESP, unless previously agreed with the HPRA. Following uploading of the documents via CESP, please email devices@hpra.ie to advise that a new performance study notification has been submitted.

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| **SECTION A: Administrative Information** |
| 1 | Is this a first notification or substantial modification?[ ]  First notification[ ]  Substantial modification |
| 2 | Enter proposed start and completion date of the performance study.Start date      Completion date       |
| 3 | If substantial modification, state previous notification date and HPRA reference number.Date      Reference no.       |
| 4 | Enter the contact details of the sponsor who is responsible for this application.Name      Address      Telephone      Email       |
| 5 | Principal investigator responsible for the conduct of the performance study in Ireland:*If more than two principal investigators are involved, please attach these details as an appendix, including details and roles for members of the investigator’s team who will be directly involved in the conduct of the study.*(i) Name      Qualification      Address      Telephone      Email      (ii) Name      Qualification      Address      Telephone      Email       |
| 6 | 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       |
| 7 | Is this part of a multi-site performance study outside Ireland? [ ]  Yes[ ]  NoIf yes, enter details of other sites. *If more than two sites, please attach details in an appendix.**Non-Irish site 1* Name      Address      *Non-Irish site 2* Name      Address       |
| 8 | Principal investigator appointed to coordinate the work in a multi-site study:Name      Qualification      Address      Telephone      Email       |
| 9 | Manufacturer's name and address, including site where the manufacture of the device is taking place:Name      Address       |
| 10 | Manufacturer's telephone, fax number and email address:Telephone      Fax      Email       |
| 11 | If the manufacturer is not based in a European state, name and contact details of authorised representative:Name      Address      Telephone      Fax      Email       |
| 12 | Enter the details of notified body/bodies who approved the quality system at the site where the manufacture of the device is taking place (as per point 9 above) (if applicable).*Notified body 1*Name      Address      Identification no.      *Notified body 2*Name      Address      Identification no.       |
| 13 | Is this application submitted in parallel with an application for a clinical trial in accordance with EU Regulation 536/2014? [ ]  Yes[ ]  NoIf yes, please provide the clinical trial reference no.Clinical trial reference no.:       |
| 14 | Has an ethics committee in Ireland provided an opinion with respect to this proposed performance study? If so, please provide a copy of the opinion.[ ]  Yes[ ]  No |
| 15 | 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 | 1. Which notified body issued the CE mark for this device?

     1. Please provide the date of the first certification and the most recent re-certification date, if applicable.

     1. What is the intended purpose of this device?

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| 5 | 1. Does the device incorporate a medicinal substance, including a human blood or plasma derivative?

[ ]  Yes[ ]  No1. Has the device been manufactured using non-viable tissue or cells of human or animal origin, or their derivatives?

[ ]  Yes[ ]  No |
| 6 | Device classification:[ ]  Class A[ ]  Class B[ ]  Class C[ ]  Class D |
| 7 | 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 the identification of the comparator device. Please also confirm that this comparator device is CE marked for this intended purpose. |

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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 | 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 there are any subjects under 18 years of age, study design and planned dates of commencement and completion of the study: |
| 5 | PSP code:  |
| 6 | PSP version number:  |
| 7 | PSP version date:  |
| 8 | Please identify the procedures, additional to those performed under the normal conditions of use of the device and that are considered invasive or burdensome, that have resulted in this performance study being subject to notification to the HPRA. *(Where necessary, append as additional information to this notification.)* |
| 9 | In the case of 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** |
| The following list is guidance only and is not exhaustive. Article 70(1) of the IVDR 2017/745 sets out the full description of documentation required for a performance study. The content and structure of documents submitted should be in line with relevant regulatory requirements and associated standards. Please provide section/page references for items in the performance study plan or document reference and page numbers for items not described in the performance study plan. |
| [ ]  | Performance study plan (PSP) (*which sets out the rationale, objectives, design, methodology, monitoring, conduct, record-keeping and the method of analysis for the performance study)*Version number      Date       |
| [ ]  | Investigator’s brochure (IB) OR Instructions for use |
| [ ]  | A copy of the opinion of the relevant Ethics Committee concerned on the details of the aspects covered by its opinion (if available) |
| [ ]  | Documents used to obtain informed consent |
| [ ]  | Description of arrangements for data protection and confidentiality of personal information |

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| **SECTION E: Declaration** |

Signed on behalf of **<sponsor>**.

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

1. As the natural or legal person responsible for the manufacture of the device for performance study, certify that the device in question conforms to the general safety and performance requirements.
2. Certify that the information and documentation submitted with this notification 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. Undertake to keep available for the competent authority for a period of 10 years (15 years for implantable devices) 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 XIII and XIV of Regulation (EU) 2017/746.
4. Certify that the sponsor consents to allow the letter acknowledging notification of this performance study to the HPRA to be copied to the Irish based investigators and the relevant Ethics Committee(s).
5. Certify that the sponsor consents to the HPRA contacting the relevant Ethics Committee(s) during the course of the review if required.
6. Confirm that the device(s) to be used in this performance study bears a valid CE mark and the proposed use in this performance study is consistent with the intended purpose of this/these CE marked medical device(s).

**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/>.