Notification of a Clinical Investigation of a CE Marked Medical Device (Article 74 MDR)

Please note that only certain clinical investigations of CE marked medical devices need to be notified to the HPRA under Article 74 of the MDR. For further guidance please see the HPRA ‘Guide to Clinical Investigations in Ireland’.

This notification form only applies to clinical investigations where the proposed use is consistent with the intended purpose of the medical device. Where a CE marked device is proposed to be used outside the scope of its intended purpose, an application to undertake a clinical investigation under Article 62 of the MDR should be made instead.

Notifications will only 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 clinical investigation notification has been submitted.

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| **SECTION A: Administrative Information** |
| 1 | Enter proposed start and completion date of the clinical investigation.Start date      Completion date       |
| 2 | Enter the contact details of the sponsor who is responsible for this application.Name      Address      Telephone      Email       |
| 3 | Principal investigator responsible for the conduct of the clinical investigation 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 investigation.*(i) Name      Qualification      Address      Telephone      Email      (ii) Name      Qualification      Address      Telephone      Email       |
| 4 | Please list the clinical investigation sites in Ireland.*If more than two sites, please attach details in an appendix.**Irish site 1* Name      Address      *Irish site 2* Name      Address       |
| 5 | Is this part of a multi-site clinical investigation 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       |
| 6 | Principal clinical investigator appointed to coordinate the work in a multi-site study:Name      Qualification      Address      Telephone      Email       |
| 7 | Manufacturer's name and address, including site where the manufacture of the device is taking place:Name      Address       |
| 8 | Manufacturer's telephone, fax number and email address:Telephone      Fax      Email       |
| 9 | If the manufacturer is not based in a European state, name and contact details of authorised representative:Name      Address      Telephone      Fax      Email       |
| 10 | 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.       |
| 11 | 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.       |
| 12 | Has an Ethics Committee in Ireland provided an opinion with respect to this proposed clinical investigation? If so, please provide a copy of the opinion.[ ]  Yes[ ]  No |
| 13 | Payment details[ ]  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 III[ ]  Class IIb[ ]  Class IIa[ ]  Class I |
| 7 | Will a comparator device be used during this clinical investigation?[ ]  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: Clinical Investigation information** |
| 1 | Full title of clinical investigation:  |
| 2 | Short title of clinical investigation (if applicable):  |
| 3 | Title for lay persons:  |
| 4 | Summary of the Clinical Investigation Plan (CIP), including the objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are any subjects under 18 years of age, design of the investigation and planned dates of commencement and completion of the clinical investigation. |
| 5 | CIP code:  |
| 6 | CIP version number:  |
| 7 | CIP 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 clinical investigation being subject to notification to the HPRA. *(Where necessary, append as additional information to this notification.)* |

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| **SECTION D: Documentation to be attached** |
| The following list is guidance only and is not exhaustive. Annex XV of the MDR 2017/745 sets out the full description of documentation required for a clinical investigation. 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 clinical investigation plan or document reference and page numbers for items not described in the clinical investigation plan. |
| [ ]  | Clinical investigation plan (CIP) (*which sets out the rationale, objectives, design, methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation)*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 investigational device, 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 clinical investigation, 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 XV of Regulation (EU) 2017/745.
4. Certify that the sponsor consents to allow the letter acknowledging notification of this clinical investigation 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 clinical investigation bears a valid CE mark and the proposed use in this clinical investigation is consistent with the intended purpose of this/these CE marked medical device(s).

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

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

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

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

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