Consultant Application for Compassionate Use of a Non-CE Marked Medical Device or an *In-Vitro* Diagnostic Medical Device

This form must be completed by the relevant consultant making the application and then submitted by email to devices@hpra.ie. Reference to a device in this form includes both medical devices and *in-vitro* diagnostic medical devices.

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| CONSULTANT and manufacturer DETAILS |
| Consultant name:     Address:     Email address:     Qualifications of consultant:      | Manufacturer name:     Address:      Email address:      |
| PATIENT DETAILS |
| Gender:      Patient initials:      Date of birth:       |
| Clinical information (Please include the following details:Patient's past medical/surgical historyDetails of patient's medical condition and current clinical status* Conclusions from recent multidisciplinary team (MDT) meetings, if any)

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| DEVICE DETAILS |
| Device name and description:      |
| Is there an equivalent CE marked device available to your knowledge?[ ]  Yes[ ]  NoIf yes, why is it not suitable on this occasion?      |
| What is the exact intended use for the device in this patient?     Has this intended use previously been validated in research or normal clinical settings?     What is the anticipated duration of patient exposure to the device?      |
| PROCEDURE DETAILS |
| What is the proposed date of device use? (If this is not known, please provide an estimated timeframe.)     If the device use is urgent, please provide detail:       |
| CLINICAL BENEFIT-RISK |
| What are the potential benefits to the patient in using this device for the intended use listed above?      |
| Please detail the potential risks to the patient in using this device and quantify, if possible:      |
| Outline the likely consequences to the patient’s condition if device is not made available for use:      |
| Further information / list supporting documentation provided, e.g. clinical case reports, published literature, any technical testing undertaken, etc.:      |
| CONSULTANT DECLARATION |
| It is my opinion that the use of this non-CE marked device is essential for this individual patient. The patient’s condition will deteriorate if the above-named non-CE marked device is not made available. There is no equivalent CE marked device available on the market that will fulfil the function required. Overall, the benefit of use of this non-CE marked device in this specific patient on this occasion outweighs the risk.I confirm that the appropriate clinical governance structures have been notified of the proposed procedure involving the device (e.g. MDT, Clinical Director, or hospital chief executive, as appropriate). I confirm that the appropriate information on the device will be made available to the patient and/or the patient’s legal representative as part of the clinician’s consent process. Consultant name:      IMC number:      Consultant signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_Consultant’s witness signature:Name:      Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |