Manufacturer Application for Compassionate Use of a Non-CE Marked Medical Device

*This form must be completed by the manufacturer of the device in question and then submitted to the by email to* [*devices@hpra.ie*](mailto:devices@hpra.ie)*.*

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| --- | --- | --- | --- | --- | --- | --- |
| MANUFACTURER and distributor DETAILS | | | | | | |
| Name and address of manufacturer: | | | | Name and address of distributor: | | |
| DEVICE DETAILS | | | | | | |
| Generic name of device: | | | | | | |
| Model: | | Serial number: | | | Lot number: | |
| Status of device: | Prototype | | Clinical investigation | | | On the market |
| Overview of device (including intended use, IFU, diagrams and photographs as necessary to explain function; these may be attached as separate documents if required): | | | | | | |
| Details of aspects of device that differentiate it from other/similar devices already on the market: | | | | | | |
| REGULATORY DETAILS | | | | | | |
| Details of any clinical investigations / performance evaluations currently using the device and names of responsible or controlling authorities (please attach any relevant supporting documentation): | | | | | | |
| Details of regulatory approval outside the EU (please provide copies of any regulatory approvals): | | | | | | |
| Details of post-market surveillance vigilance or recalls issues to date: | | | | | | |
| Outline of intention to affix the CE mark to this device at a later date: | | | | | | |
| DETAILS OF PROPOSED USE | | | | | | |
| Detail the reason for requesting use of the non-CE marked device: | | | | | | |
| Details of risk/benefit analysis for the use of the non-CE marked device (please include risk/benefit analysis along with the application): | | | | | | |
| Outline whether the intended use on this occasion is consistent with previous licensed or research use: | | | | | | |
| Further information / list supporting documentation provided: | | | | | | |
| MANUFACTURER DECLARATION | | | | | | |
| Please tick one box, as appropriate:  I have read Regulation (EU) 2017/745 regarding medical devices and am aware of my legal responsibilities under the legislation.  I have read Irish Statutory Instrument S.I. No. 304 of 2001 regarding *in-vitro* diagnostic medical device and am aware of my legal responsibilities under the legislation.  I,      , representing the manufacturer, am aware that permission is being sought for the use of this non-CE Marked device in one patient. I have discussed the proposed use of this non-CE marked device with the medical/surgical consultant intending to use the device. I have made available to the consultant all relevant data relating to the use of this device in this way with specific attention to the risk/benefit analysis. The device has been designed, manufactured and tested with due consideration for the relevant ‘General Safety and Performance Requirements’ and other relevant legislative requirements of the applicable Statutory Instrument/Regulation. | | | | | | |
| Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:  <print name>  <print title>  Manufacturer’s witness signature:  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:  <print name>  <print title> | | | | | | |