Application for the placing on the market of a non CE-marked device in relation to UK’s withdrawal from EU, in the interest of the protection of health

**The manufacturer must complete this section:**

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| --- |
| Name and address of manufacturer:  Name and address of Authorised Representative within EU (if relevant/known):  Name and address of the distributor (if relevant/known): |
| Generic name of device: |
| Type of device: |
| Device model/ Catalogue/ Series/ Lot numbers on the label: |
| Information and status on change of notified body, or  Information and status on current notified body, which are in the process of moving to an EU27 country |
| Details of aspects of device that differentiate it from other devices already on the market: |
| Further information including a risk analysis, identification of hazards, estimation of risks and how such risks have been addressed, together with information to support a positive risk benefit analysis: |
| Information on the CE-marking of the device by a UK notified body according to the EU directives prior to No Deal Brexit (Date)  Attach a copy of the EC-certificate from a UK notified Body |
| Information on where the device will be used eg. department, clinic, hospital, Region: |
| Signed: Date:  Name(printed): |

Application for the placing on the market of a non CE-marked device in relation to UK’s withdrawal from EU, in the interest of the protection of health

**The healthcare professional must complete this section:**

|  |
| --- |
| Name and address of Healthcare Institution:  Name of healthcare professional:  Email:  Telephone: |
| Reason for the device's necessity due to protection of health: |
| Further information: |
| Declaration:  It is my opinion that the device is intended to achieve an improvement of Danish patient conditions and that there is no other CE- marked device available on the market that will fulfil the function required.  Signed: Date:  Name(printed): |