

**EU IVDR Article 110 extension confirmation (if you have not obtained a letter from your notified body)**

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| --- | --- | --- |
| **Manufacturer Name (‘Manufacturer’)** | **Manufacturer Address** | **MHRA Account Number** |
|  |  |  |
| **UKRP/Northern Ireland Authorised Representative Name (if applicable)** | **UKRP/NI Authorised Representative Address** | **MHRA Account Number** |
|  |  |  |

I/we declare that:

* the CE certificate(s) listed below were issued under the EU In vitro diagnostic Devices Directive (98/79/EC) on or after 25 May 2017 and were still valid on 26 May 2022 **AND**
* the conditions for extension of the validity of the CE certificate(s) (under the EU In vitro diagnostic Devices Regulation (2017/746) (EU IVDR) Article 110) set out below have been met in relation to the CE certificates as listed in the table below

**[Complete the relevant table below]**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **CE Certificate number/s**  | **Notified Body that issued the CE certificate**  | **Expiry date/s** | **Notified Body currently responsible for surveillance** | **Extended validity date(s) for NI market** | **Extended validity date(s) for GB market** |
| 1. That, in the case of a certificate that **expired before 9 July 2024** I/we/the manufacturer has a signed contract with a notified body that pre-dates the original expiry of the certificate
 |  | *Enter Name & Number* |  | *Enter Name & Number*  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **CE Certificate number/s**  | **Notified Body that issued CE certificate**  | **Expiry date/s** | **Derogation Reference Number & issuing Competent Authority****(if any)** | **Notified Body currently responsible for surveillance** | **Extended validity date(s) for NI market** | **Extended validity date(s) for GB market** |
| 1. That, in the case of a certificate that **expired before 9 July 2024,** no such contract (set out in (a) above) was signed before the date of certificate expiry, and the Manufacturer was granted in respect of the device:
* a derogation from the conformity assessment procedures under EU IVDR Article 54(1) **OR**
* a period of time to carry out conformity assessment in accordance with EU IVDR Article 92(1)
 |  | *Enter Name & Number*  |  |  | *Enter Name & Number* |  |  |

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|  | **CE Certificate number/s**  | **Notified Body that issued the certificate** | **Expiry date/s** | **Notified Body currently responsible for surveillance** | **Extended validity date(s) for NI market** | **Extended validity date(s) for GB market** |
| 1. The CE certificate(s) **was due to expire on or after 9 July 2024**, and remains valid by virtue of EU IVDR Article 110(2).
 |  | *Enter Name & Number*  |  | *Enter Name & Number* |  |  |

**Signed by Manufacturer:**

**Name of Signatory Position of Signatory Date**

**Signed by UK Responsible Person/Northern Ireland Authorised Representative (if applicable):**

**Name of Signatory Position of Signatory Date**