|  |  |  |  |
| --- | --- | --- | --- |
|  |   |  | Version 1 |
|  | **Notified Body Position Paper** |
| Standardized confirmation letter for correcting or complementing information on existing IVDD certificates |

The purpose of this document is to establish Notified Bodies harmonized approach for a written confirmation that the implementation of the changes does not represent a significant change in design or intended purpose under IVDR Article 110(3) and that the related IVDD certificate remains valid until 26 May 2025, at the latest. A written confirmation corrects or complements information on an existing certificate but does not represent the issuance of a “supplemented certificate” as this is prohibited as mentioned in Section 3. This position paper follows the approach of MDCG 2022-XX Guidance on significant changes regarding the 1 transitional provision under Article 110(3) of the IVDR.

1. **Confirmation letter to be used by Notified Bodies on a voluntary basis**

|  |  |
| --- | --- |
| **Directive:** | **<e.g. 98/79/EC, Annex IV>** |
| **Organisation:** | **<Client Name>** |
| **Registered place of business:** | <Client Address> |
| **Certificate number:** | <No.> | **Validity:** | <Max. 2025-05-26> |
| **Scope:** | <Scope of e.g. 98/79/EC Annex IV Certificate> |
| **Change description:** | <e.g. removal of products from certificate> |
| **Date of change:** | <Date of change coming into effect> |

To whom it may concern,

(optional) <Name of Notified Body, NBxxxx> is a Notified Body according to Regulation (EU) 2017/746 on medical devices.

<Name of Notified Body, NBxxxx> declares that pursuant to Article 110 (1) of Regulations (EU) 2017/746, since 26th May 2022, no certificate under the In-Vitro Diagnostics Medical Device Directive 98/79/EC is allowed to be issued anymore. Consequently, pursuant to guidance MDCG 2022-XX (Guidance on significant changes regarding the 1 transitional provision under Article 110(3) of the IVDR), this decision is valid together with and complements the above-mentioned certificate.

We as a Notified Body will continue to perform the surveillance activities for certificates according to <e.g.Directive 98/79/EC> issued by <Name of Notified Body, NBxxxx >, which are still valid, as laid out in Regulation (EU) 2017/746, Article 110 (3).

<Name of Notified Body, NBxxxx > hereby confirms that the above-mentioned EC-Certificate has been issued to the above-mentioned client and is still valid with the mentioned changes.

(optional) <Name of Notified Body, NBxxxx.> hereby confirms that the following products/product types <were removed from [CERTIFICATE NUMBER]:/ are covered under> [CERTIFICATE NUMBER]:

1. [name product model 1]
2. [name product model 2]
3. [name product model 3]

<Name of Notified Body, NBxxxx > hereby confirms that the afore mentioned change is not considered a significant change in the design and/or intended purpose as described in Regulation (EU) 2017/746, Article 110 (3). The evaluation of documents related to the change has been completed and approved.

Date:

Signature(s)