**Disclaimer:**

This document was prepared by the Ad Hoc Commission “In Vitro Diagnostic Medical Devices” of the *Association of the Scientific Medical Societies in Germany* (AWMF) in accordance with Regulation (EU) 2017/746 Art. 5 (5). The document is not legally binding and serves solely as a recommendation for implementing the IVDR requirements in health institutions that manufacture and use devices. The document reflects the current state of knowledge at the time it was written and does not claim to be complete. The authors assume no liability whatsoever.

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Author: Hoffmüller, Petra (representing the German Society of human genetics, GfH)

**Declaration**

**under Art. 5 (5) EU Regulation on in vitro diagnostic medical devices  
(EU) 2017/746 (IVDR) for in-house production of IVD in health institutions**

***Erklärung***

***nach Art. 5 (5) der EU-Verordnung über In-vitro-Diagnostika (EU) 2017/746 (IVDR) zur Eigenherstellung eines IVD in Gesundheitseinrichtungen***

We declare under our sole responsibility that the product listed below and manufactured by us by way of in-house production

*Wir erklären in alleiniger Verantwortung, dass das unten aufgeführte Produkt, welches im Wege der Eigenherstellung von uns hergestellt wird,*

|  |  |
| --- | --- |
| Product designation, product name  *Produktbezeichnung, Produktname* |  |
|  |  |
| Product code, product number  *Produkt-Code, Produktnummer* |  |
|  |  |
| Health institution  *Gesundheitseinrichtung* | **Name**  **Adresse** |

complies with all requirements of the IVD Regulation (EU) 2017/746, Annex I 'General Safety and Performance Requirements', which apply to it.

The following requirements do not apply: Annex I section/s….

Justification:

*allen Anforderungen der IVD-Verordnung (EU) 2017/746, Anhang I ´Grundlegende Sicherheits- und Leistungsanforderungen´, entspricht, die anwendbar sind.*

*Die folgenden Anforderungen finden keine Anwendung: Anhang I, Abschnitt/e ….*

*Begründung:*

The product was manufactured by us in our own premises on a non-industrial scale and is operated solely in our healthcare institution.

*Das Produkt wurde in unseren eigenen Räumlichkeiten von uns in nicht industriellem Maßstab gefertigt und wird ausschließlich in unserer Gesundheitseinrichtung betrieben.*

|  |  |
| --- | --- |
| Device classification according to Annex VIII *Produktklassifizierung nach Anhang VIII* | Class X  *Klasse x* |

|  |  |  |  |
| --- | --- | --- | --- |
| Place and date of issue:  *Ort und Datum der Erstellung:* |  | Managing Director  *Geschäftsführer* |  |
|  |  |  |  |
| Musterstadt, den |  | Quality Manager  *Leiter Qualitätsmanagement* |  |