

## EU Declaration of Conformity

Neuhausen, 2025-05-27

|                             |                                                                               |
|-----------------------------|-------------------------------------------------------------------------------|
| <b>Product Group Number</b> | <b>1006 Cellodent Swabs non-sterile</b> (scope see table 1)                   |
| <b>Manufacturer</b>         | IVF HARTMANN AG<br>Victor-von-Bruns-Strasse 28<br>8212 Neuhausen, Switzerland |

We herewith declare under our sole responsibility that the product listed above, first placed on the market by IVF HARTMANN AG, satisfy the applicable provisions of the following listed legislation. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

### Applied legislative act

#### Medical Device Regulation (EU) 2017/745

|                                  |                                                             |                           |
|----------------------------------|-------------------------------------------------------------|---------------------------|
| High Level Intended Purpose      | Non-active, non-implantable devices for wound and skin care |                           |
| Classification                   | Risk Class                                                  | Rule                      |
|                                  | Class I                                                     | Rule 4, indent 1          |
| Conformity Assessment Procedure  | Article 52 (7)                                              |                           |
| Notified Body                    | n.a.                                                        |                           |
| Single Registration Number       | Manufacturer: CH-MF-000015962                               |                           |
| Swiss Single Registration Number | Manufacturer: CHRN-MF-20000305                              |                           |
| Basic UDI-DI                     | 76116001006LJ                                               |                           |
| EMDN                             | Code                                                        | Term                      |
|                                  | M020299                                                     | Non-woven gauzes – others |
| GMDN                             | 48131                                                       | Non-woven gauze pad       |

IVF HARTMANN AG

i.V.



**Dr. Heinrich Giegrich**  
Head of RA & Quality

Valid until: 2029-12-31

i.V.



**Susanne Frei**  
Senior Regulatory Affairs Manager

Table 1: List of products falling under the respective Product Group Number:

| REF    | Description                 |
|--------|-----------------------------|
| 263010 | Cellodent Swab 4x5cm P1008  |
| 263030 | Cellodent Swab 4x5cm P15120 |