# EU Certificate

**Quality Management System**
**REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III**

TÜVRheinland®

Registration No.: HZ 1754014-1

Manufacturer:
**Udo Heisig GmbH**
**The Disposables Company**
Hermann-Oberth-Str. 17
85640 Putzbrunn
Germany

EUDAMED Single Registration No.: DE-MF-000009334

Products: Products of class I, steril:

T030101 - COVER CAPS, INSTRUMENTARY AND EQUIPMENTS

The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Authorised representative(s): N/A

| Certificate history | | |
|---|---|---|
| Revision: | Description: | Issue date: |
| 0 | Initial issue | 2022-09-15 |
| | | |
| | | |

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1103749-40

Effective date: 2022-09-15

Expiry date: 2027-06-22

Issue date: 2022-09-15

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Roland Gruber
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.