

# EU Certificate

## Production Quality Assurance REGULATION (EU) 2017/745 on Medical Devices Annex XI Part A

Registration No.: DZ 1625800-1  
Manufacturer: KERMA Verbandstoff GmbH  
Ziegelstr. 29  
09661 Hainichen  
Germany

EUDAMED Single  
Registration No.: DE-MF-000006351

### Products:

Products of class I, sterile:

M010102 PURE COTTON  
M020101 COTTON GAUZES, CUT  
M020102 COTTON GAUZES, FOLDED  
M020199 COTTON GAUZES - OTHERS  
M020299 NON-WOVEN GAUZES - OTHER  
M040301 EYE PADS, COTTON OR NON-WOVEN  
MATERIALS  
M9099 GENERAL AND SPECIALIST MEDICAL DEVICES –  
OTHER (SUTURE PATCHES SEE H900102)

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

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.

If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 1197364-100  
Effective date: 2026-05-04  
Expiry date: 2031-05-03  
Issue date: 2026-05-03



Dr. Karsten Kluge  
TÜV Rheinland LGA Products GmbH  
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This certificate can be validated on <https://www.certipedia.com>

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



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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REGULATION (EU) 2017/745 on Medical Devices  
Annex XI Part A**

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Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Re-certification. Replaces certificate DZ 1625800-1 rev. 0 issued 2021-05-04.	2026-05-03



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