

## Declaration of Conformity

according to Annex VII of directive 93/42/EWG of medical products

**LEINA - WERKE GmbH**  
**Maueler Feld 1**  
**51570 Windeck**

professes that the following product

**LEINATEX bandage cloth**  
Size: 40 cm x 60 cm, 60 cm x 80 cm  
aluminized, sterile

is produced on the demands of a quality management system after EN ISO 13485 and corresponds to all used demands of the directive 93/42/EWG for medical devices. The product is classified as class I-sterile, according to annex IX, rule 4 of directive 93/42/EWG.

The applied norms and documents are taken from the corresponding technical documentation.

Monitoring and certification in accordance with Annex V of Directive 93/42/EEC is carried out by the notified body TÜV Rheinland LGA Products GmbH, Tillystrasse 2, 90431 Nürnberg, ID number **0197**.

This declaration of conformity is valid until exhibition of a revised declaration of conformity after changing the product or until the expiry date of the certificate issued by the notified body. The expiration date is August 04, 2023.

Windeck, 06<sup>th</sup> June 2021

LEINA-WERKE GmbH  
Managing Director  
Thorsten Steinhauer

  
**LEINA-WERKE GmbH**  
Maueler Feld 1  
DE-51570 Windeck-Rosbach