Declaration of Conformity

according to Annex VII of Council Directive 93/42/EEC of medical products

We, the company

LEINA - WERKE GmbH
Maueler Feld 1
D - 51570 Windeck

declare, that this EU – declaration of conformity was issued under our sole responsibility and applies to the medical devices listed below. We ensure, that these medical devices are produced under the requirements of a quality management system according to EN ISO 13485 and that they comply with all applicable requirements of the Council Directive 93/42/EEC.

Compressive Bandage

DIN 13151-K 6 cm x 8 cm **DIN 13151-M** 8 cm x 10 cm **DIN 13151-G** 10 cm x 12 cm
single sealed
sterile

The product is classified as Class I-sterile, according to annex IX, rule 4 of Council Directive 93/42/EEC.

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

Monitoring and certification in accordance with Annex V of Council 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 (DD 601299530001) issued by the notified body. The expiration date of the certificate is August 04, 2023.

Windeck, 25th July 2022

LEINA-WERKE GmbH
Managing Director
Thorsten Steinhauer

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

EU-Declaration of Conformity

According to EU regulation 2017/745 on medical devices

We, the company

LEINA-WERKE GmbH
Maueler Feld 1
D - 51570 Windeck

SRN: DE-MF-000005358

declare, that this EU – declaration of conformity was issued under our sole responsibility and applies to the medical devices listed below. We ensure, that these medical devices are produced under the requirements of a quality management system according to EN ISO 13485 and that they comply with all applicable requirements of the EU-regulation 2017/745 on medical devices (MDR).

Plaster-Set for DIN-fillings

DIN 13164, DIN 13157 and DIN 13167
with REF-Number
REF 75203

Basic UDI-DI: **4011166WSVFolieAcrylatF2**

Intended purpose of the product:
Plasters and adhesive bandages for medical care and to protect small skin injuries

Risk Class of the product: Class I (acc. to MDR Annex VIII, Rule 4)

The products are manufactured and released in accordance with the specifications, applied standards and normative documents defined in the associated technical documentation. The products bear the CE conformity marking.

This EU declaration of conformity applies in conjunction with the release documentation of the manufactured batches belonging to the product and is valid until a revised declaration of conformity is issued after the product has been changed.

Windeck, 03.11.2022

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

LEINA-WERKE GmbH
Managing Director
T. Steinhauer

LEINA-WERKE GmbH
EIN STARKER PARTNER BRINGT SICHERHEIT

Version: 01
Datum: 23.02.2021
Seite: 1 von 1

EU-Declaration of Conformity

according to EU regulation 2017/745 on medical devices.

We, the company

LEINA-WERKE GmbH
Maueler Feld 1
51570 Windeck

SRN: - not yet allocated -

declare, that this EU - declaration of conformity was issued under our sole responsibility and applies to the medical devices listed below.
We assure that these medical devices are produced under the requirements of a quality management system according to EN ISO 13485 and that they comply with all applicable requirements of the EU-regulation 2017/745 on medical devices (MDR).

Fixation Bandage DIN 61634-FB

With the REF-Number(s)
REF 60050 to REF 60054

Basis UDI-DI: **4011166LEINA-61634-FBKE**

Intended use of the product:
The purpose of these bandages is to fix wound dressings when treating injuries with the aid of bandage clips or plaster strips. In addition, the attachment of support splints and the use as a light support and compression bandage.

Risk class of the product: Class I (according to MDR Annex VIII, rule 1)

The products are manufactured and released in accordance with the specifications, applied standards and normative documents defined in the associated technical documentation. The product bears the CE conformity marking.

This EU declaration of conformity applies in conjunction with the release documentation of the manufactured batches belonging to the product and is valid until a revised declaration of conformity is issued after the product has been changed.

Windeck, the 25.05.2021

LEINA-WERKE GmbH
Managing Director
T. Steinhauer

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

Declaration of Conformity

according to Annex VII of Council Directive 93/42/EEC of medical products

We, the company

LEINA - WERKE GmbH
Maueler Feld 1
D - 51570 Windeck

declare, that this EU – declaration of conformity was issued under our sole responsibility and applies to the medical devices listed below. We ensure, that these medical devices are produced under the requirements of a quality management system according to EN ISO 13485 and that they comply with all applicable requirements of the Council Directive 93/42/EEC.

Leinacomp – Gauze compresses
made of Bandage gauze DIN EN 14079
5 cm x 5 cm / 7,5 cm x 7,5 cm / 10 cm x 10 cm
Single/double sealed
sterile

The product is classified as Class I-sterile, according to annex IX, rule 4 of Council Directive 93/42/EEC.

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

Monitoring and certification in accordance with Annex V of Council 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 (DD 601299530001) issued by the notified body. The expiration date of the certificate is August 04, 2023.

Windeck, 03rd November 2022

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

LEINA-WERKE GmbH
Managing Director
Thorsten Steinhauer

LEINA-WERKE GmbH
EIN STARKER PARTNER BRINGT SICHERHEIT

Version: 01
Datum: 23.02.2021
Seite: 1 von 1

EU-Declaration of Conformity

according to EU regulation 2017/745 on medical devices.

We, the company

LEINA-WERKE GmbH
Maueler Feld 1
51570 Windeck

SRN: - not yet allocated -

declare, that this EU - declaration of conformity was issued under our sole responsibility and applies to the medical devices listed below.
We assure that these medical devices are produced under the requirements of a quality management system according to EN ISO 13485 and that they comply with all applicable requirements of the EU-regulation 2017/745 on medical devices (MDR).

rescue blanket

With the REF-Number(s) REF 43000 and REF 43001

Basis UDI-DI: LEINA-RD

Intended use of the product:
Heat and cold protection for first aid

Risk class of the product: Class I (according to MDR Annex VIII, rule 1)

The products are manufactured and released in accordance with the specifications, applied standards and normative documents defined in the associated technical documentation. The product bears the CE conformity marking.

This EU declaration of conformity applies in conjunction with the release documentation of the manufactured batches belonging to the product and is valid until a revised declaration of conformity is issued after the product has been changed.

Windeck, the 25.05.2021

LEINA-WERKE GmbH
Managing Director
T. Steinhauer

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

LEINA-WERKE GmbH
EIN STARKER PARTNER BRINGT SICHERHEIT

Version: 01
Datum: 23.02.2021
Seite: 1 von 1

EU-Declaration of Conformity

according to EU regulation 2017/745 on medical devices.

We, the company

LEINA-WERKE GmbH
Maueler Feld 1
51570 Windeck

SRN: - not yet allocated -

declare, that this EU - declaration of conformity was issued under our sole responsibility and applies to the medical devices listed below.
We assure that these medical devices are produced under the requirements of a quality management system according to EN ISO 13485 and that they comply with all applicable requirements of the EU-regulation 2017/745 on medical devices (MDR).

Triangular cloth DIN 13168-D

With the REF-Number(s) REF 62100

Basis UDI-DI: 4011166LEINA-DTG9

Intended use of the product:
Heat and cold protection for first aid

Risk class of the product: Class I (according to MDR Annex VIII, rule 4)

The products are manufactured and released in accordance with the specifications, applied standards and normative documents defined in the associated technical documentation. The product bears the CE conformity marking.

This EU declaration of conformity applies in conjunction with the release documentation of the manufactured batches belonging to the product and is valid until a revised declaration of conformity is issued after the product has been changed.

Windeck, the 25.05.2021

LEINA-WERKE GmbH
Managing Director
T. Steinhauer

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