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).

Adhesive Tape with Zinc rubber adhesive

with REF-Number(s)

Reference	Description
74000-74003; 74010-74015	Adhesive Tape Mediplast
74050-74052; 74060-74062	Adhesive Tape Medisilk
74100-74102	Adhesive Tape Mediflex
74150-74152; 74160-74162	Adhesive Tape Medipor

Basic UDI-DI: **4011166HPSpulenZKKM2**

Intended purpose of the product:
Fixation of wound dressings (compresses, bandages), as well as venous catheters, drains or probes.
Not intended for direct contact with injured skin.

Risk Class of the product: Class I (acc. 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 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

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

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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

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.

LEINA-Dressing DIN 13152
40 cm x 60 cm (BR), 60 cm x 80 cm (A), 80 cm x 120 cm (B)
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

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).

Triangular bandage DIN 13168-D

with REF-Number(s)

Reference	Description
62100	136 cm x 96 cm x 96 cm

Basic UDI-DI: **4011166DREIECKTUCHZF**

Intended purpose of the product:
Triangular bandages are intended for use as fixatives (for example for sterile compresses, bandages or fracture immobilization materials). They can also be used for padding or as a carrying aid in first aid. Can also be used as an arm sling or to make ring pads and various non-sterile bandages.

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, 25.07.2022

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).

First Aid Vinyl Gloves DIN EN 455

With the REF-Number(s)
REF 43010 to 43015

Basis UDI-DI: **4011166LEINA-HS-VinylHD**

Intended use of the product:

Protection against contamination for patient and rescuer during 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