EU-Declaration of Conformity

Wolfstein, 27.05.2021

We herewith declare,

Object of declaration: **Compression bandages, short stretch, permant-elastic, non-cohesive, (NOVA Varix, product 547)**

Short description: Short stretch compression bandage to be used on intact skin

Intended Purpose:
This reusable, non-sterile, permanent elastic, short-stretch compression bandage can be used for long-term treatment in compression therapy of chronic venous diseases, thromboembolic venous diseases, oedemas and other indications. This product is indicated in compression therapy with an ABPI of 0.8-1.3 only. Moreover, it can be used as a support and relief bandage in musculoskeletal injuries. The product is to be applied on intact skin only.

which have been first placed on the market by **KOB GmbH, Lauterstr. 50, 67752 Wolfstein, Germany,**

meet the applicable provisions, in particular the General Safety and Performance Requirements of the following EU-legislation:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The Conformity Assessment Procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

The product has been identified as a medical device in risk class I according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

This EU-Declaration of Conformity is issued under the sole responsibility of the **KOB GmbH.**

Basic UDI-DI:
4004221547XL

SRN (Single Registration Number): **DE-MF-000005043**

Name Dr. Achim Hehl	Name Simone Heck
Function CEO	Function Head of Regulatory Affairs
Signature	Signature i.V.

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Geschäftsführer:
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Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/745	Class. Rule	GMDN	Term GMDN	CND	Term CND
40547094 109600	I	1	61223	Pressure bandage, non-latex, non-sterile, reusable	M0304010103	Elastic Compression Bandages, Non-Adhesive, Short Extensibility (<70%)
40547095 109601	I	1	61223	Pressure bandage, non-latex, non-sterile, reusable	M0304010103	Elastic Compression Bandages, Non-Adhesive, Short Extensibility (<70%)

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