

EU-Declaration of Conformity

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Wolfstein, 12.11.2024

We herewith declare,

Object of declaration: **Compression multi-components, (Mepi Press 2 Lite, product 732)**

Short description: Pressure-reduced 2-component compression system

Intended Purpose:

The 2-component compression system is a single-use, non-sterile medical device used by healthcare professionals in clinical and home environment. It can be used for long-term compression therapy which requires a reduced level of compression (ABPI 0.6-0.8), or for patients unable to tolerate full compression, or as part of a step-up approach, for the treatment of: Mixed etiology (arterial-venous) leg ulcers, Chronic venous diseases (e.g. venous leg ulcers), Thromboembolic venous diseases, Oedema (e.g. Lymphoedema), Other Indications. 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:

4004221732XH

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

Name Dr. Achim Hehl	Name Simone Vierung
Function CEO	Function Head of Regulatory Affairs
Signature 	Signature 

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Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/745	Class. Rule	GMDN	Term GMDN	EMDN	Term EMDN
40732010 300011	I	1	58983	Compression bandaging kit	M030499	Elastic Bandages, Support and Compression - Others
40732011 300016	I	1	58983	Compression bandaging kit	M030499	Elastic Bandages, Support and Compression - Others

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