

EU-Declaration of Conformity

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Wolfstein, 12.11.2024

We herewith declare,

Object of declaration: **Compression multi-components, (Mepi Press 2, product 730)**

Short description: Multilayer compression system to be used on intact skin

Intended Purpose:

This single use, non-sterile 2-Component-System can be used for the long- term treatment in compression therapy of chronic venous diseases, thromboembolic venous diseases, oedemas and other indications. This 2-component-system is indicated with an ABPI of 0.8-1.3 only. When applied on top of each other, the two components together form a compression system that can be left in place for up to 7 days, depending on the condition of the wound and the wear time of the wound dressing used. 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.

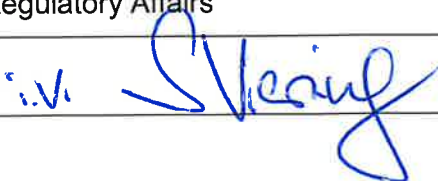
The product has been identified as a medical device in risk class I according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

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

Basic UDI-DI:

4004221730XD

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
40730067	I	1	58983	Compression bandaging kit	M030499	Elastic Bandages, Support and Compression - Others
300001						
40730068	I	1	58983	Compression bandaging kit	M030499	Elastic Bandages, Support and Compression - Others
300006						

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Geschäftsführer:
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