

EU-Declaration of Conformity

Wolfstein, 11.06.2021

We herewith declare,

Object of declaration: Compression bandages, short stretch, textile-elastic, cohesive, (product 104, Askina Forte)

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

Intended Purpose:

This single use, non-sterile, textile elastic, cohesive 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 support and relief bandage in musculoskeletal injuries.

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

meets 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:
4004221104WE

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

Name Dr. Achim Hehl	Name Simone Heck
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	CND	Term CND
9057013	I	1	10284	Pressure bandage, non-latex, non-sterile, single-use	M0304010201	Elastic Compression Bandages, Cohesive, Low Extensibility (<70%)
9057021	I	1	10284	Pressure bandage, non-latex, non-sterile, single-use	M0304010201	Elastic Compression Bandages, Cohesive, Low Extensibility (<70%)

Effective

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Geschäftsführer:
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