

EU-Declaration of Conformity

Wolfstein, 11.06.2021

We herewith declare,

Object of declaration: Zinc paste bandages, (products 306, Askina Zinkleimbinde)

Short description: Zinc paste bandage to be used on intact skin

Intended Purpose:

This single use, non-sterile zinc paste bandage is used for semi-rigid support and compression dressings. It can be applied for long-term treatment in compression therapy of chronic venous diseases, thromboembolic venous diseases, oedemas and other indications. This zinc paste bandage is indicated with an ABPI of 0.8-1.3 only. Moreover, it can be used as a support and relief bandage following injuries of the postural and locomotor system and as follow- up treatment when plaster casts are removed.

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:
4004221306WU

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

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

EU-Declaration of Conformity

Page 2/2

Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/745	Class. Rule	GMDN	Term GMDN	CND	Term CND
9052208	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
9052216	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
9052224	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide

Effective 

KOB GmbH
Lauterstraße 50
67752 Wolfstein, Germany

Geschäftsführer:
Dr. Achim Hehl (Vorsitzender)
Dr. Christian Ferck

Amtsgericht Kaiserslautern
HRB 32894

info@kob.de
www.kob.de
T +49 6304 74-0