

EU-Declaration of Conformity

Page1/2

Wolfstein, 11.11.2020

We herewith declare,

Object of declaration: Zinc paste bandages, (Urgozink elast, Urgozink Bi-elast; products 306, 310)

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
4004221310WK

Registration Number: DE/0000040253 (Registration Number DIMDI)

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



EU-Declaration of Conformity

Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/745	Class. Rule	GMDN	Term GMDN	CND	Term CND
40306049	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
40306050	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
40306051	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
40306052	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
40306053	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
40306054	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide
40310027	I	1	10284	Pressure bandage, non-latex, non-sterile, single use	M03020201	Medicated Bandages, with Zinc Oxide