

EU-Declaration of Conformity

Wolfstein, 20.05.2021

We herewith declare,

Object of declaration: **Fixation bandages, non-cohesive (KREWI Mull; product 564)**

Short description: Elastic fixation bandage to be used on intact skin

Intended Purpose:

These single-use non-sterile elastic fixation bandages are used for long-term treatment for retention of all kinds of primary and secondary dressings, splints, casts, catheters and canulas (etc.) particularly on joints as well as on conical and round parts of the body. As well as stabilisation of muscles, tendons, ligaments and joints with low immobilisation effect. 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,**

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:
4004221564XL

Registration Number: DE/0000040253 (Registration Number DIMDI)

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

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Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/1745	Class. Rule	GMDN	Term GMDN	CND	Term CND
40564844 600004	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Monoextensible
40564845 600006	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Monoextensible
40564846 600008	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Monoextensible
40564847 600010	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Monoextensible