

EU-Declaration of Conformity

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Wolfstein, 15.12.2020

We herewith declare,

Object of declaration: **Fixation bandages, cohesive (Zehenbinde Rinki; product 184)**

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

Intended Purpose:

These single-use, non-sterile cohesive, elastic fixation bandages are used for long-term treatment for retention of all kinds of primary and secondary dressings, splints, casts, padding material, catheters and cannulas (etc.) particularly on joints as well as on conical and round parts of the body, for 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:

4004221184X6

Registration Number: DE/0000040253 (Registration Number DIMDI)

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| 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 |
|---------------------|---|-------------|-------|--------------------------------|-------------|--|
| 40185029 7441303 | I | 1 | 58964 | Non-adhesive retention bandage | M0303010201 | Elastic Bandages, Fixing, Cohesive, Monoextensible |
| 40185030 7441301 | I | 1 | 58964 | Non-adhesive retention bandage | M0303010201 | Elastic Bandages, Fixing, Cohesive, Monoextensible |
| 40185031 7441302 | I | 1 | 58964 | Non-adhesive retention bandage | M0303010201 | Elastic Bandages, Fixing, Cohesive, Monoextensible |
| 40185090 7441311 | I | 1 | 58964 | Non-adhesive retention bandage | M0303010201 | Elastic Bandages, Fixing, Cohesive, Monoextensible |
| 40185091 7441312 | I | 1 | 58964 | Non-adhesive retention bandage | M0303010201 | Elastic Bandages, Fixing, Cohesive, Monoextensible |