

EU-Declaration of Conformity

Wolfstein, 21.06.2021

We herewith declare,

Object of declaration: **Fixation bandages, cohesive (products 184, 186; Askina kohäsive Fixierbinde LF, Askina Haft Color)**

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

4004221186XA

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
9058125	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058133	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058141	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058028	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058613	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058516	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058419	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058311	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058915	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058249	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058257	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058222	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible

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Geschäftsführer:
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HRB 32894

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9058230	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058203	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058214	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058320	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
9058338	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible

Effective

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