

EU-Declaration of Conformity

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Wolfstein, 11.06.2021

We herewith declare,

Object of declaration: **Fixation bandages, non-cohesive (products 367, 564; Askina Elast fine, Askina Elast)**

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:

4004221367XG

4004221564XL

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

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) 2017/745	Class. Rule	GMDN	Term GMDN	CND	Term CND
9046046	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9046062	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9046089	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9046100	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9046127	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9045040	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9045066	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9045082	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9045104	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9047069	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9047085	I	1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction

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Geschäftsführer:
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9047107		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048227		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048235		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048243		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048111		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048120		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048138		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048146		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction
9048154		1	58964	Non-adhesive retention bandage	M0303010101	Elastic Bandages, Fixing, Non-Adhesive, Extensible in one direction

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