

EU-Declaration of Conformity

Wolfstein, 20.04.2022

We herewith declare,

Object of declaration: **Fixation bandages, cohesive (Urgoflex latexfrei, Urgoflex color latexfrei, Urgomull haft latexfrei, Urgomull haft color latexfrei; products 180, 186, 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. 186/180 also for skin protection as first layer under adhesive dressings. 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,**

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:

4004221180WW
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 

EU-Declaration of Conformity

Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/745	Class. Rule	GMDN	Term GMDN	EMDN	Term EMDN
40180215 513040	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184948 510864	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184949 510866	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184950 510861	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184951 510862	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184952 510863	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184953 510865	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184954 510860	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184955 510854	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184960 510855	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184961 510853	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184962 510851	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40184963 510852	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible



EU-Declaration of Conformity

40184964 510850	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186386 513033	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186387 513034	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186388 513035	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186389 513043	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186390 513044	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186391 513045	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186392 513046	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186393 513047	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186394 513048	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186395 513049	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186396 513050	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186397 513036	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186398 513037	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186399 513038	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible
40186400 513032	I	1	58964	Non-adhesive retention bandage	M0303010201	Elastic Bandages, Fixing, Cohesive, Monoextensible

