EU-Declaration of Conformity

Wolfstein, 11.11.2020

We herewith declare,

Object of declaration: **Support and relief bandages, permanent-elastic, non-cohesive, (Urgolast universal; product 592)**

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

Intended Purpose:
These reusable, non-sterile, permanent elastic support and relief bandages are used for support, relief, fixation and compression dressings. They are indicated for long- term treatment of musculoskeletal injuries, for post fracture treatment and blunt injuries. 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:
4004221592XR

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.

KOB GmbH
Lauterstraße 50
67752 Wolfstein, Germany

Geschäftsführer:
Dr. Achim Hehl (Vorsitzender)
Dr. Christian Ferck

Amtsgericht Kaiserslautern
HRB 32894

info@kob.de
www.kob.de
T +49.6304.74-0

EU-Declaration of Conformity

Product code/ref nr	Risk class acc. to Annex VIII of Regulation (EU) 2017/745	Class. Rule	GMDN	Term GMDN	CND	Term CND
40592820	I	1	61223	Pressure bandage, non-latex, non-sterile, reusable	M03040201	Elastic Support Bandages, Non-Adhesive
40592821	I	1	61223	Pressure bandage, non-latex, non-sterile, reusable	M03040201	Elastic Support Bandages, Non-Adhesive
40592822	I	1	61223	Pressure bandage, non-latex, non-sterile, reusable	M03040201	Elastic Support Bandages, Non-Adhesive
40592823	I	1	61223	Pressure bandage, non-latex, non-sterile, reusable	M03040201	Elastic Support Bandages, Non-Adhesive

KOB GmbH
Lauterstraße 50
67752 Wolfstein, Germany
0

Geschäftsführer:
Dr. Achim Hehl (Vorsitzender)
Dr. Christian Ferck

Amtsgericht Kaiserslautern
HRB 32894

info@kob.de
www.kob.de
T +49.6304.74-