EU - Declaration of Conformity

GELSENKIRCHENER WERKSTÄTTEN

We, **Gelsenkirchener Werkstätten, Braukämperstraße 100, 45899 Gelsenkirchen**, represented by Claudia Gutheil, PRRC according to Art.15 MDR, declare under our sole responsibility that the medical devices of the product group

GEVAK Evacuation System

Basic UDI-DI: 42519185 750221011 BN

complies with the relevant provisions of Regulation (EU) 2017/745 (MDR) on medical devices and, where applicable, other relevant Union legislation

The product group includes the following medical devices			
Commercial name	**Article No**	**Commercial name**	**Article No**
GEVAK Evacuation Sheet white	8010 100 14	**GEVAK-B** Evacuation Seat - anthracite	8010 100 15
GEVAK Evacuation Sheet white Special size	8010 100 22	**GEVAK-B** Evacuation Seat with hose handles	8010 100 18
GEVAK Evacuation Sheet white with longer fixation wings	8010 600 18	**GEVAK-ST** Evacuation mattress	8010 100 16

Intended use of the product group: The GEVAK evacuation system is used to evacuate a lying or immobile person in dangerous situations. According to Annex VIII, Rule 1 MDR, all devices in the product group are class 1 medical devices and the applicable essential safety and performance requirements according to Annex I MDR are fulfilled. A conformity assessment procedure according to Annex II & III MDR has been carried out.

Applicable harmonized standards, national standards, or other regulatory documents:

DIN EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes

DIN EN ISO 14971 – Medical devices – Application of risk management to medical devices

DIN EN 1865-1 – Patient handling equipment used in road ambulances

This EU Declaration of Conformity is valid until **25.05.2025**

Claudia Gutheil

Gelsenkirchen, the 25.05.2024

Claudia Gutheil
PRRC according to Art. 15 MDR

Manufacturers SRN: DE-MF-000013108