

EU - Declaration of Conformity

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 **25th of May 2024**

Claudia Gutheil

Gelsenkirchen, the 25th of May 2023

Claudia Gutheil

PRRC according to Art. 15 MDR

Manufacturers SRN: DE-MF-000013108

Version 1.0	Erstellt: TC	Freigabe RA: TC 25.05.2023	Freigabe VP: CG 25.05.2023	QM-System nach EN ISO 13485
Datei: GW CE KE-EN GEVAK 05-23			Anlage: 16.03.2021	Stand: 25.05.2023 Seite 1 von 1
Firma: Gelsenkirchener Werkstätten gGmbH			© Castner Consulting – Medizinische Systemberatung	