

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

GERET Rescue Sheet according to EN 1865

Basic UDI-DI: 42519185 750185020 E8

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.	Commercial name	Article No.
GERET orange Rescue Sheet	8010 100 05	GERET black Rescue Sheet	8010 100 35	GERET light white Rescue Sheet	8010 100 31
GERET orange Rescue Sheet with hose handles	8010 100 06	GERET black Rescue Sheet with hose handles	8010 100 36	GERET light Plus white Rescue Sheet	8010 100 29
GERET orange Rescue Sheet with hose handles & foot muff	8010 100 07	GERET black Rescue Sheet with hose handles & foot muff	8010 100 33	GERET light camouflage B Rescue Sheet	8010 100 32
GERET blue Rescue Sheet	8010 600 17	GERET light black Rescue Sheet	80 10 100 26	GERET light Plus camouflage B Rescue Sheet	8010 100 30
GERET blue Rescue Sheet with hose handles	8010 600 08	GERET light Plus black Rescue Sheet	8010 100 28	GERET – XXL Heavy load Rescue Sheet	8010 100 09
GERET blue Rescue Sheet with hose handles & foot muff	8010 600 14			GERET – BREIT Fire Rescue Sheet	8010 100 10

Intended use of the product group: Rescue and transport of injured and sick persons.

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 **26th of May 2024**

Claudia Gutheil

Gelsenkirchen, the 07th of July 2023

Claudia Gutheil
PRRC according to Art. 15 MDR

Manufacturers SRN: DE-MF-000013108

Version 1.1	Erstellt: TC	Freigabe RA: TC 07.07.2023	Freigabe VP: CG 10.07.2023	QM-System nach EN ISO 13485
Datei: GW CE KE-EN GERET 07-23	Anlage: 16.03.2021		Stand: 07.07.2023	Seite 1 von 1
Firma: Gelsenkirchener Werkstätten gGmbH			© Castner Consulting – Medizinische Systemberatung	