

EU - Declaration of Conformity

We, **Gelsenkirchener Werkstätten, Braukämpferstraße 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® blue Rescue Sheet with hose handles & foot muff	8010 600 14	GERET® light black Rescue Sheet	80 10 100 26
GERET® orange Rescue Sheet with hose handles	8010 100 06	GERET® black Rescue Sheet	8010 100 35	GERET® light Plus black Rescue Sheet	8010 100 28
GERET® orange Rescue Sheet with hose handles & foot muff	8010 100 07	GERET® black Rescue Sheet with hose handles	8010 100 36	GERET® – XXL Heavy load Rescue Sheet	8010 100 09
GERET® blue Rescue Sheet	8010 600 17	GERET® black Rescue Sheet with hose handles & foot muff	8010 100 33	GERET – BREIT® Fire Rescue Sheet	8010 100 10
GERET® blue Rescue Sheet with hose handles	8010 600 08				

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 **25.05.2027**

Claudia Gutheil

Gelsenkirchen, the 25.05.2026

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: GuC 25.05.2026	QM-System nach EN ISO 13485	
Datei: GW CE KE-EN PG GERET 05-26.docx			Anlage: 16.03.2021	Stand: 25.05.2026	Seite 1 von 1
Firma: Gelsenkirchener Werkstätten gGmbH			© Castner Consulting – Medizinische Systemberatung		