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

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 **25.05.2025**

Claudia Gutheil

Gelsenkirchen, the 25.05.2024

Claudia Gutheil
PRRC according to Art. 15 MDR

Manufacturers SRN: DE-MF-000013108