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

GERUT® Transfer Sheet

Basic UDI-DI: 42519185 75018021020 GJ

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.**
GERUT® Transfer Sheet white	8010 100 03	GERUT® Transfer Sheet olive	8010 100 01
GERUT® Transfer Sheet blue	8010 100 24	GERUT® Transfer Sheet orange	8010 100 02

Intended use of the product group: The GERUT® transfer sheet is intended exclusively for the gentle transfer of a patient. 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