

# EU-Declaration of conformity

within the meaning of the Regulation (EU) 2017/745 (MDR)



We declare under our own responsibility the conformity of the following products with the Regulation (EU) 2017/745 (MDR). According to annex VIII, rule 1, this products are class I products:

**Make: OP-FIX-Band (patient restrainer), Basis-UDI-DI 426046972GE0174**

Type designation	UDI-DI	Type designation	UDI-DI	Type designation	UDI-DI
GE 01-17x2,5	4260469720017	GE 01-32x5 GM	4260469720208	GE 01-80x5 FI	4260469720352
GE 01-17x2,5 FI	4260469720031	GE 01-35x5 NFI	4260469720215	GE 01-80x5 FV	4260469720345
GE 01-17x2,5 FV	4260469720024	GE 01-36x8 WV	4260469720222	GE 01-80x5 N	4260469720369
GE 01-28x3	4260469720062	GE 01-40x5	4260469720239	GE 01-80x5 NFI	4260469720376
GE 01-28x3 FI	4260469720093	GE 01-40x5 FI	4260469720253	GE 09-30x5 FI	4260469721007
GE 01-28x3 FV	4260469720079	GE 01-40x5 FV	4260469720246	GE 09-32x5 G	4264069721045
GE 01-30x5	4260469720123	GE 01-40x5 WV	4260469720307		
GE 01-30x5 FI	4260469720147	GE 01-40x5 WVE	4260469720314		
GE 01-30x5 FV	4260469720130	GE 01-40x5 WVS	4260469720291		
GE 01-30x5 N	4260469720161	GE 01-40x5 N	4260469720260		
GE 01-30x5 NFI	4260469720178	GE 01-40x5 NFI	4260469720277		
GE 01-30x5 FIM	4260469720154	GE 01-42x5 FI	4260469721243		
GE 01-30x5 FN	4260469720130	GE 01-42x5 FIG	4260469721250		
GE 01-32x5 G	4260469720192	GE 01-80x5	4260469720338		

We confirm that above-mentioned products have been developed, designed and manufactured in accordance with annex I of Regulation (EU) 2017/745 (MDR).

Applied harmonized standards, national standards or other normative documents:

Verordnung (EU) 2017/745 (MDR)	Medizinproduktegesetz (MPG)	EN 15223-1:2015-08
EN 1041:2013-12	EN ISO 10993-1:2010-04	EN 15986:2011-05
EN ISO 10993-10:2014-10	EN ISO 14971:2013-04	

The necessary technical documentation according to annex II and III of Regulation (EU) 2017/745 (MDR) is completely available.

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**SRN:** DE-MF-000006156

This document is valid until May 31, 2023 or until the next change.

Gerd Riester, owner

Jungingen, 01.06.2021