EU-Declaration of confirmity

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: Catheter holders, urinebag holders, Basis-UDI-DI 426046972GE047A

Type designation	UDI-DI	Type designation	UDI-DI	Type designation	UDI-DI
GE 04-1001	4260469720741	GE 04-1004	4260469720772		
GE 04-1002	4260469720758				
GE 04-1003	4260469720765				

We confirm that the 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 ISO 15223-1
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 or Regulation (EU) 2017/745 (MDR) is completely available.

Manufacturer: GERWING Medizinprodukte Gerd Riester e.K.
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D-72417 Jungingen

SRN: DE-MF-000006156

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

Jungingen, 01.06.2021

Gerd Riester, owner