

## EU Declaration of Conformity

We, Heinrich Caroli GmbH, Eichrodtstr. 13, 77933 Lahr, Germany, declare on our own responsibility that our medical devices of Class 1 according to Annex VIII Rule 1 comply with all requirements of the EU Medical Devices Regulation (2017/745). Conformity is documented in our technical documentation and is confirmed by the CE marking.

The conformity assessment procedure was carried out in accordance with EU Regulation 2017/745 as per Annex II and Annex III. According to Annex I of Regulation (EU) 2017/745 (MDR), all applicable essential safety and performance requirements are met. This applies to the listed product groups using the following standards and legal regulations:

- EU-Regulation 2017/745 (MDR)
- DIN EN ISO 13485:2021
- Medical Devices Implementation Act (MPDG)

Product Group	Basis-UDI-DI	Purpose
Dynamic hinged splints	42519138DynaGelenkAQ	Treatment of joint contractures of the upper and lower extremities
Static hinged splints	42519138StatGelenkP4	Treatment of joint contractures of the upper and lower extremities
Fractional ligament	42519138BruchbandDA	Treatment of reducible hernias
Suspensors	42519138Suspensorium8D	Support of the testicle in case of water hernia or painful irritation
Support bandages	42519138StuetzbandagenJ8	Bandage (orthosis) to support and relieve the lumbar spine
Symphysis Belt	42519138SymphysengurtL7	Stabilisation of the pelvic ring
Trunk bandages	42519138RumpfbandageE5	Circular compressive support bandage for the thorax
Wrist bandages	42519138HandgelenkbandGX	Orthosis stabilising support of the wrist joint
Cervical support	42519138Cervicalstuetze2F	Orthosis for stabilisation of the cervical spine
Foot lifter orthoses	42519138FussheberQ8	Orthoses for the care of patients with mild to moderate weakness of the foot lifter.
Ostomy Products	42519138Stomaprodukte44	Support of the stoma through circular compression
Colostomy Products	42519138ColostomieWX	Recording of the Bowel movement with colostomy and ileostomy
Pressure Pads	42519138PelotteVM	Pressure pads used in combination with a bandage on the body
Manu Control 3D	42519138ManuControl3dPX	Treatment of joint contractures of the fingers and wrist joint

SRN:

DE-MF-000005517

Validity:

Until a product named in the table is changed

Place and date

Lahr, 31.07.2023

Surname, first name / position:

Caroli, Heinrich / Managing Director

Signed for and on behalf of the

Heinrich Caroli GmbH  
Eichrodtstr. 13  
77933 Lahr

Signature 