

EC Declaration of Conformity

Manufacturer: KayserBetten GmbH & Co KG Rieper Str. 12 D-29683 Bad Fallingbostel Germany SRN: DE-MF-000006910

We declare under our sole responsibility that the products listed below comply with the relevant provisions of the following regulations.

Product designation	Risk class (EU) 2017/745 Annex VIII	Basis UDI-DI
KayserBetten IDA	I	4260389611DAGU

Purpose:

Children's care beds are used for chronically ill and/or physically/mentally impaired children and adolescents for nursing, therapeutic care and as sleeping and reclining places.

Regulations: (EU) 2017/745 Medical Devices Regulation

Conformity assessment procedure (EU) 2017/745: Annex II, Annex III, Annex IV, Annex V

Applied applicable parts of the standards: BS EN 50637:2018 BS EN 60601-1:2013 BS EN 60601-2-52:2016 BS EN 716-1:2019

In the event of relevant changes to the above-mentioned medical devices, this Declaration of Conformity loses its validity in accordance with the requirements of EK-Med Decision 3.9 A4 of the ZLG.

Bad Fallingbostel, 23.06.2022

Torsten Kappenberg / Managing Directo

Jens Lübben / Head of Medical Technology, PRRC

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