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 LOTTE	I	426038961LOTTEES

Purpose:
The KayserBett LOTTE serves as a sleeping and reclining place and as a barrier-free changing place for the care of infants and toddlers by physically/impaired wheelchair-bound parents or third persons.

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 Director

Jens Lübben / Head of Medical Technology, PRRC