

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
Changing table	I	426038961WTUD

Purpose:

Changing tables offer for healthy or chronically ill and/or physically/mentally impaired infants or small children the use of hygienic care and changing facilities.

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:

DIN EN 12221-1/2:2013 DIN EN 60601-1:2013

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, 03.05.2021

Torsten Kappenberg / Managing Directo

Jens Lübben / Head of Medical Technology, PRRC