

EU Declaration of Conformity

(01) 8720892016607(11)260101(10)2601

The manufacturer: E.E.H. ug (Haftungsbeschränkt)
An der Esseite 215 – 4
48599 Gronau
Germany

SRN: DE-MF-000045659

Responsible: Mr. Marco Hoonhorst, Director

Declares under his sole responsibility, that the following product:

Product name: Evatex evacuation sheet Model Vario **Evatex**
Intended use: Safe and rapid evacuation of people who are bedridden or can not
Get out of bed easily/quickly (in hospitals, nursing homes and
residential groups).
Basic UDI-DI: 6580989V90200SR
Risk class: Class 1 (Annex VIII, rule 1, MDR)
Variants/models:

Size	UDI-DI
90 x 200	08720892016607
80 x 200	08720892016652
90 x 190	08720892016676
100 x 200	08720892016621
120 x 200	08720892016638

is in conformity with the (applicable) requirements of the Medical Device Regulation (EU) 2017/745 (MDR).

The following (harmonised) standards were used:

- NEN-EN-ISO 14971:2019 (Application of risk management to medical devices)
- NEN-EN-ISO 15223-1: 2021 (Symbols to be used on medical device labels)
- NEN-EN-ISO 20417:2021, cor. 2022-04 (Medical devices – Information to be supplied by the manufacturer)

Mr. Marco Hoonhorst, Director

Date: December 31, 2025

Place: Gronau

