



EU Declaration of Conformity

The manufacturer: E.E.H. ug (haftungsbeschränkt)
Oberstr 3
47829 Krefeld
Germany

Responsible: Mr. Marco Hoonhorst, Director

Declares under his sole responsibility that the following product:
Basic UDI-DI: 118287308720892016607XL

Product name: Evatex evacuation sheet Model Vario

Risk class: Class I (Annex VIII, rule 1, MDR)

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

The following (harmonised) standards were used:
- NEN-EN-ISO 14971 (application of risk management to medical devices)

Krefeld, Germany

Mr. Marco Hoonhorst, Director

Datum: 15-12-2022

Marco Hoonhorst