

EG Declaration of Conformity

We,

Technicare Ridderkerk BV as follows:

Company Name: TechniCare Ridderkerk B.V.
Trade name: TechniCare
Address: Nikkelstraat 24
Postal code: 2984AM
Country of origin: NL- Nederland
GS1 Prefix Code: 87202992680
SRN Code: NL-MF-000005899

Hereby, we confirm that this declaration concerns the CE-marked product in question under sole responsibility of the company.

Product: Mobilyzer 2
Article code: 22.003.01
SRN Code: NL-MF-000005899
UDI Code: 8720648522604
GMN Code: 8720299268022.003.01SM
Basic UDI-DI Code (01) 8720648522604 (17)xxxxxx(10)xxx(21)xxxx
Product classification 10005844- medical device

It is classified as a Medical Device Class I according to the MDR Regulation 2017/745/EU regarding Medical Devices and complies with the essential requirements of the directives.

- Verordening (EU) 2017:745
- NEN-EN-ISO 13485:2016
- NEN-EN-ISO 14971:2019
- NEN-EN-ISO 15223-1:2021
- NEN-EN-ISO 21856:2022

Products covered by this Declaration of Conformity have been added to the product reference list (see Annex I).

Signing:

Date: 11-5-2024



Name: Arjan van de Voorde

Title: CEO