

EC Declaration of Conformity

We,

Technicare Ridderkerk B.V. as follows:

Company name TechniCare Ridderkerk B.V.

Trade name TechniCare
Address Nikkelstraat 24
Postal code 2984 AM Ridderkerk
Country of origin Netherlands (NL)
GS1 Prefix Code 87202992680
SRN Code NL-MF-000005899

declare that this declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Treatment chair Proceed

Article number 20.001

UDI-DI code 8720299268050

GMN code 8719327397420.001.013V

Basic UDI-DI Code (01) 8720299268050 (17)xxxxxx(10)xxx(21)xxxx

Product classification 10005844 - Medical Devices

This product, including its accessories, conforms to the Medical Device Regulation (EU) 2017/745 Class I.

The following harmonized standards and technical specifications have been applied:

- MDR (EU) 2017:745
- NEN-EN-ISO 13485:2016
- NEN-EN-ISO 14971:2019
- NEN-EN-ISO 15223-1:2021
- NEN-EN-ISO 21856:2022
- NEN-EN-IEC 60601-1:2006
- NEN-EN-IEC 60601-1-6:2010
- NEN-EN-IEC 60601-1-2:2015

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

Signing:

Date: 30-5-2024

Place: Ridderkerk, Netherlands

Name: Arjan van de Voorde Title: CEO