

EU Declaration of Conformity

Medical Devices Regulation (EU) 2017/745 (MDR)

Declaration of Conformity acc. Annex IV

For
Class 1 Medical Devices

Manufacturer's name: Van Raam Reha Bikes B.V.

Manufacturer's address: Guldenweg 23
7051 HT Varsseveld
The Netherlands

Product: Therapy tricycle

Device Name: Kivo Plus tandem

Basic-UDI: 8719327508725

Part number: 377-XXXX

The product of the declaration described above complies with the Essential Requirements of Medical Devices Regulation (EU) 2017/745 (MDR – Class 1 Medical Devices). The products are labelled with the CE-Mark according to this directive.

If the product of declaration, as delivered, is equipped with the Silent Elektro System, it also complies with the Essential Requirements of Machine Directive 2006/42/EG, including the Essential Requirements of the EMC Directive 2014/30/EU and is in conformity with the requirements of the following harmonized standard: NEN-EN 15194:2017 Cycles – Electrically power assisted cycles – EPAC Bicycles - part 4.2 Electrical requirements.

Signed for and on behalf of Van Raam Reha Bikes B.V.

Varsseveld, 25-05-2021

Place, Date of Issue


Signature, Name, Position