

# 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:** OPair 3

**Basic-UDI:** 8719327508787

**Part number:** 383-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

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**Place, Date of Issue**

  
**Signature, Name, Position**