

CE & UKCA Declaration of Conformity

Medical devices regulations (EU 2017/745 MDR) and (UK MDR 2002)

For

Class 1 Medical Devices

Manufacturer's name : Van Raam Reha Bikes B.V.
Manufacturer's address : Guldenweg 23
: 7051 HT Varsseveld
: The Netherlands

Representative in UK : Van Raam Ltd

Product : Therapy bicycle
Device Name : Balance 2
Basic-UDI : 8720299493964
Part number : 388-XXXX

The product of the declaration described above complies with the Essential Requirements of: EU Medical Devices Regulations 2017/745 (MDR - Class 1) and UK Medical Devices Regulation 2002 (UK MDR 2002 Class 1). The products are labelled with the CE Mark according EU 2017/745 and UKCA-Mark according to EU Exit Regulations 2020, SI2020/1478.

If the product of declaration, as delivered, is equipped with the Silent Elektro System, it also complies with the Essential Requirements of:

Machinery Directive : EU CE 2006/42/EU
: UKCA Machinery (Safety) Reg. SI 2008/1597
Radio Equipment : EU CE 2014/53/EU
: UKCA Radio Equipment Reg. SI 2017/1206
EMC Directive : EU CE 2014/30/EU
: UKCA Electromagnetic Compatibility Reg. SI 2016/1091
Low Voltage : EU CE 2014/35/EU
: UKCA Electrical Equipment (Safety) Reg. SI 2016/1101
RoHS : EU CE 2011/65/EU and 2015/863/EU
: UKCA Electrical and Electronic Equipment Reg. SI 2012/3032

For used harmonized standards see page 3

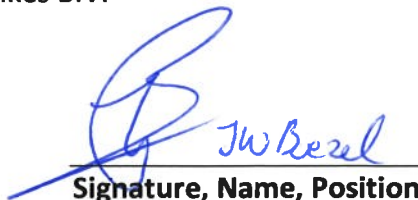
And is in conformity with the requirements of the following harmonized standard:

EPAC Bicycles : BS - NEN - EN 15194:2017 Electrically power assisted cycles
part 4.2 Electrical requirements.

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

Varsseveld, 14-12-2022

Place, Date of Issue


Signature, Name, Position

CE & UKCA Declaration of Conformity

Manufacturer: Kunshan ST Electronics Co., Ltd

Manufacturer's address: No.198 Huatao Road Qiandeng
Kunshan
China

Importer: Van Raam Reha Bikes B.V.

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

Product: LI-ION BATTERY CHARGER

Device Name: Silent charger Li-ion 36V 6A with Rosenberger connector

Part number: 103-5999

This declaration of conformity is issued under the sole responsibility of the importer. The product of the declaration described above complies with the Essential Requirements of:

EMC Directive : EU CE 2014/30/EU
: UKCA Electromagnetic Compatibility Reg. SI 2016/1091

Low Voltage : EU CE 2014/35/EU
: UKCA Electrical Equipment (Safety) Reg. SI 2016/1101

RoHS : EU CE 2011/65/EU and 2015/863/EU
: UKCA Electrical and Electronic Equipment Reg. SI 2012/3032

For used harmonized standards see page 3

The products are labelled with the CE and UKCA Mark according to these directives.

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

Varsseveld, 14-12-2022

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Used harmonized standards


Standards RED – 2014/53/EU & UK SI 2017/1206	Name
ETSI EN 301 511 V12.5.1	GSM / GPRS (Telematica)
IEC 62479:2010	Bluetooth (2.4 GHz) (Display)
ETSI EN 300 328 V2.2.2	Bluetooth (2.4 GHz) (Display)
ETSI EN 303 413 V1.1.1	GLONASS / GPS (Telematica)
EN 62209-2:2010/A1:2019 / EN 50566:2017	SAR test (Battery/ Telematica)

Standards EMC & ESD 2014/30/EU & UK SI 2016/1091	Name
Draft ETSI EN 301 489-52 V1.1.2 (2020-12) ETSI EN 301 489-19 V2.1.1 (2019-04) Draft ETSI EN 301 489-19 V2.2.0 (2020-09) ETSI EN 301 489-17 V3.2.4 i.c.m. ETSI EN 301 489-1 V2.2.3 (2019-11)	Telematica and bluetooth
EN 55014-1:2021 / EN 55014-2:2021 EN 61000-3-2:2019 / EN 61000-3-3:2013 +A1:2019	Battery and charger combination
EN 15194:2017 Annex C	EPAC
ISO 11452-8:2015	Immunity to magnetic fields (bike)
EN 61000-4-39:2017	Immunity to Radiated fields in close proximity (bike)

Standards LVD – 2014/35/EU & UK SI 2016/1101	Name
IEC 62368-1:2018	Electrical safety

Varsseveld, 14-12-2022

Place, Date of Issue


 Signature, Name, Position