



EasyRoller

Declaration of Conformity (CE)

DHF-0030-02

Document Summary:

Declaration of conformity for EasyRoller and EasyRoller Pool.

	Name & Roll	Sign & Date
Reviewed		
Approved		

1. Declaration of Conformity

1.1. Manufacturer

Easy Roller AS
Hagebyveien 40
3734 Skien
Norway

1.2. Device

- EasyRoller

REF: ER

Basic UDI-DI: 709006211EASYROLLER2R

- Intended use:

By being metal free, the EasyRoller wheelchair will not affect nor be affected by magnetic resonance imaging's magnetic fields or metal detectors. Using EasyRoller porters will be able to transport PRM throughout the entire hospital environment without any restrictions. Passing of security gates is done without any intimidating manual control of the person with reduced mobility.

- EasyRoller Pool

REF: ERP

Basic UDI-DI: 709006211EASYROLLER2R

- Intended use:

The person with reduced mobility can be transported from the reception area through showers and with the chair submerged in the swimming pool the person with reduced mobility can do exercising in water with the wheelchair at hand. The EasyRoller is not affected by any use in a Sauna environment.

1.3. Classification

EasyRoller and EasyRoller Pool are classified as Class 1 Medical Device according to MDR Regulation (EU) 2017/745 Annex VIII, Rule 1.

1.4. Conformity Assessment

MDR, Regulation (EU) 2017/745, Art. 19, Annex IV & V.

1.5. EC Representative

N/A

1.6. Single Registration Number

NO-MF-000010301

1.7. GMDN Code

58086

1.8. EORI Number

DE1807838

We, the manufacturer declares herewith under our sole responsibility that the above mentioned products meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. All supporting documentation is retained on the premises of the manufacturer.

Place: Fredrikstad	Date: 01Nov2023	Signature of Chief Executive Officer: <u><i>Knut Bernhard Iversen</i></u> <small>Knut Bernhard Iversen (Nov 1, 2023 15:45 GMT+1)</small>
Place: Fredrikstad	Date: 01Nov2023	Signature of Person Responsible for Regulatory Compliance: <u><i>Vijeai Arunthavarajah</i></u> <small>Vijeai Arunthavarajah (Nov 1, 2023 15:43 GMT+1)</small>

2. Revision History

Revision number	Changes
01	Initial Release
02	Update reflecting MDR








EasyRoller Declaration of Conformity

Final Audit Report

2023-11-01

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