

**EasyRoller AS**

Declaration of Conformity for:

EasyRoller - Manual Wheelchair in 100 % thermoplastics

Version	Compiled by	Date	Description
001	Knut Bernhard Iversen, Managing Director	Jan 25. 2020	First Issue
002	Knut Bernhard Iversen, Managing Director	Feb 02. 2021	Update/clarifications

European Communities Council Directive 93/42/EEC Concerning Medical Devices.

The Undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE mark may be affixed.

General product name: EasyRoller – manual wheelchair in 100% thermoplastics

Manufacturer: Easy Roller AS,
Hagebyveien 40, 3734 Skien Norway

Variants: EasyRoller Standard and EasyRoller Pool (see annex)

Intended Use: Transport of PRM in institutions and Hospitals

Standards tested to: ISO 7176 and EN 12183

MDD Directive Classification NO: Class 1 Device

Notified Body: N/A

MDD Assessment Route: Constructed by Ekerdesign.com, Tested by The Swedish Institute of assistive Technology, GMDN registration, Self-certification by Annex VII. EC declaration of Conformity and Article 14. Registration of persons responsible for placing devices on the market.



EasyRoller


Signed :

Skien, Norway Date: Feb. 08 2021

Knut Bernhard Iversen (Managing Director)

Signature above is the legal person with responsibility for the design manufacture, packaging and labelling before the device is placed on the market under the EasyRoller AS name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

**Statements/Comments/Clarifications:**

- *Each EasyRoller produced are individually numbered.*
- *The Technical documentation for EasyRoller are filed and maintained by the manufacturer.*
- *Product manufacturing instructions, product user instructions, drawings and specifications are filed with the manufacturer and/or its subcontractors.*
- *Instructions for use, including applicable technical information is available for each device.*
- *A risk analysis is maintained. General requirements for safety have been covered by testing and the product conform to the standards referred to on page 1 of this document.*
- *EasyRoller is MR Safe* 
- *EasyRoller contains no PVC*
- EasyRoller non metallic wheelchair contains none of the hazardous substances specified in the **ROHS** directive.
- The **WEEE** directive is not applicable for EasyRoller non metallic wheelchair
- On **REACH** – EasyRoller non metallic wheelchair is made from materials which are available on the open European plastics market, where material certificates are available. None of the materials have any consequences for personal use or for the environment

GMDN Code: **58086**

This declaration is valid for the mentioned product marked with **CE-sign**. Any modifications made to the product without our approval shall invalidate this declaration.

ANNEX - Model Listing

<i>EasyRoller Standard</i>	<i>For use at Hospitals – Institutions – Prisons – Airports – Nuclear Power Plants</i>
<i>EasyRoller Pool</i>	<i>For use at Swimming pools – Leisure parks – Saunas – Cryogenic Saunas</i>