



Declaration of conformity.

Acc.: European MDR directive and directive 93/42 EEC, annex VII
as amended by 2007/47/EC

Manufacturer:
Baldertech AS
EU MDR SRN No: NO-MF-000003446

Address:
Follummoveien 60
3516 Hønefoss, Norway

Product: **Electric Powered Wheelchair**
EU MDR Device Classification: Class 1

Model: **Balder Finesse 390 and attachment**
EU MDR UDI_DI: 7090057413901

Applied harmonized standards for electric powered wheelchairs:

No.	Name
EN 12182:2012	Technical aids for disabled persons. General requirements and test methods
EN 12184:2014	Electric powered wheelchairs, scooters and their chargers, requirements and test methods
ISO 7176-1:1999	Determination of static stability
ISO 7176-2:2001	Determination of dynamic stability of electric wheelchairs
ISO 7176-3:2013	Determination of efficiency of brakes
ISO 7176-4:2008	Determination of energy consumption of electric wheelchairs
ISO 7176-6:2001	Determination of maximum speed, acceleration and retardation of electric wheelchairs
ISO 7176-7:1998	Measurement of seating and wheel dimensions
ISO 7176-8:1998	Requirements and test methods for static, impact and fatigue strengths.
ISO 7176-9:2009	Climatic tests for electrical wheelchairs
ISO 7176-10:2008	Determination of obstacle-climbing ability of electric wheelchairs
ISO 7176-14:2008	Power and control systems for electric wheelchairs
ISO 7176-15:1996	Requirements for information disclosure, documentation and labelling
ISO 7176-16:2012	Resistance to ignition of upholstered parts - Requirements and test methods
ISO 7176-19:2008	Wheelchair Frontal Impact Test
ISO 7176-21:2009	Requirements and test methods for electromagnetic compatibility (EMC) of electrical powered wheelchairs and motorized scooters
ISO 10542-5:2004	Wheelchair Tiedown Frontal Impact Test
ISO 14971:2007	Medical Devices – Application of risk management to medical devices
EN ISO 13485:2016	Medical Devices – Quality management systems

Other applied relevant harmonized standards:

EN 60601-1-2:2007	Electromagnetic compatibility (EMC)
EN ISO 10993-1:2003	Biological test – Synthetic leather
EN ISO 10993-5:1999	Toxicity – Synthetic leather
EN 717-1:2004	Formaldehyd – “Wood Based Panels”
ISO 14184-1:2011	Formaldehyd – «Content of free Formaldehyd in fabric to the wheelchairs”
ISO 1041:2006 parts 1-2	Ignition source: smouldering cigarette and match-flame equivalent

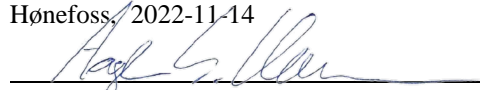
Balder wheelchairs are multi-functional electric wheelchairs which are very comfortable and highly flexible in terms of functionality. Balder wheelchairs combine the qualities of an outdoor chair with the flexibility of an indoor model and are designed for daily use in all situations.

Owner’s manual and mounting instructions is available in Norwegian and English

CE-marked from date:
1998-12-01

We hereby declare that the wheelchair and its attachment are approved in accordance to the European MDR directive and the medical device directive 93/42 EEC. Technical documentation confirming that the product is in accordance to the requirements is available on request.

Hønefoss, 2022-11-14


Aage Skov Clausen
Managing director