

Declaration of Conformity



Manufacturer: ROLTEC el-kørestole A/S
Single Registration Number: DK-MF-000002196
Address: Lægårdsvej 13, DK-8520 Lystrup
Contact: info@roltec.dk

Product Name: ROLTEC Heavy Duty
Type / Model: D67CHD
Basic UDI 5745000346DHD48

Wheelchair Class: **Class B**,
wheelchairs sufficiently compact and manoeuvrable for some indoor environments and capable of negotiating some outdoor obstacles

Class / Rule / Annex: **Class I , Rule 13, Annex VIII**
(according to regulation 2017/745/EU)

Intended purpose: ROLTEC electric wheelchairs are designed for people who have a partial or full walking disability, but whose sight, physical and mental capacity enables them to use an electric wheelchair.

We hereby solemnly declare that the above-mentioned products comply with the following Regulation, Directive and harmonized standards:

European Medical Device Regulation 2017/745

Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)

Harmonized standards in connection to Regulation 2017/745/EU:

EN 12184:2014	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
ISO 7176-19: 2011	Crash test – 4-Dahl Docking
ISO 7176-19: 2011	Crash test – 4-Point
EN ISO 14971:2012	Application of risk management to medical devices
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 1021-1:2014	Furniture. Assessment of the ignitability of upholstered furniture. Ignition source smouldering cigarette
EN 1021-2:2014	Furniture. Assessment of the ignitability of upholstered furniture. Ignition source match flame equivalent

Date: 29.09.2022

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