

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 PYTHON
Type / Model: F87D
Basic UDI 574500034600FX5
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

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