



EC DECLARATION OF CONFORMITY

Manufacturer:

Indes Production Management B.V.
Pantheon 28
7521 PR Enschede
The Netherlands
SRN: NL-MF-000000051

Products: Wheeldrive

Trade names / Models	Basic UDI-DI
Indes Wheeldrive Left Indes Wheeldrive Right Empulse Wheeldrive Left Empulse Wheeldrive Right	Basic UDI-DI: 87193275115WHEELDRIVE5H

Classification: Class I according to rule 13

Indes Production Management B.V. declares that the above mentioned product(s):

- meet the relevant provisions of following regulations:
 - Medical Device Regulation (EU) 2017/745
- meet the relevant provisions of following directives:
 - RoHS 2011/65/EU
- comply to the applicable general safety and performance requirements as defined in Annex I of Regulation (EU) 2017/745.
- have technical documentation available in accordance with Annex II and Annex III of Regulation (EU) 2017/745.
- are designed, manufactured and tested in accordance with the quality management system of Indes B.V. which complies to EN ISO 13485:2016 and art.10-9 of Regulation (EU) 2017/745.

Applied standards:

Reference	Title
EN 14971:2012	Medical devices - Risk management
EN 12183:2014	Manual wheelchairs - Requirements and test methods
EN 12184:2014, Class B	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
ISO 7176-14:2008	Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
ISO 7176-19:2008	Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles
ISO 7176-21:2009	Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
EN 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 62304:2006	Medical device software - Software life-cycle processes

This declaration of conformity is issued under the sole responsibility of Indes Production Management B.V.

Niek Kottink, Managing Director


Enschede
The Netherlands

Date: 25 mei 2021