



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU)
2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 60601-1-2:2015+A1:2020
EN 60601-1:2006+A1:2013
EN 12184: 2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: Power Wheelchair

Model:

N5513A,N5513B,N5513C,N5519,N5519D,W5211,W5213,
W5213B,W5213C,W5213D,W5216,W5216A,W5216B,W5217,
W5517,W5517A,W5520,W5521,W5521B,W5521C,
W5211B,N5515,N5515A,N5516,N5516A,W5521A,N5525,
W5526,N5901,W5907,W5536,W5536A,W5536B,N5913,
Q50 R Carbon, N5915, N5916, N5517A, N5917, N5909,
W5905, W5905A

EMDN: Y122127

GMDN: 40840

Basic UDI-DI: 697076597PW001QM

Classification: Class I, According to Rule 13, Annex VIII,
Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.