



DECLARATION OF CONFORMITY
 ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
 Fascinatlo Boulevard 522, Unit 1.7,
 2909VA Capelle aan den IJssel, The
 Netherlands
 SRN: NL-AR-000000247

Manufacturer

Name: XUZHOU HEABENS MEDICAL
 TECHNOLOGY CO., LTD.
 Address: No. 2 Industrial Concentration Zone,
 Liucheng Avenue, Weimiao Town, Peixian County,
 Xuzhou, Jiangsu.
 SRN:CN-MF-000031737
Product Information

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: 2023
 EN ISO 10993-23: 2021
 EN 12184:2022
 EN 60601-1-2:2006/A2:2021
 EN 60601-1-2:2015/A1:2021
 EN 62366-1:2015

Name: Electric Wheelchair
 Model: 0030; 0031; 0032; DYN20AHBSD01;
 DYN20AHBSD02; DYN20AHBSD03
 0010, 0011, 0012, 0014, 0016, 0017, 0020, 0021,
 0040, 0041, 0042, 0043, 0043P, 0045, 0050,
 0060, 0061, 0062, 0070, 0071, 0080, 0081, 0090,
 0091, 0092, 0190, 0191, 0192, 0120, 0121, 0122
 EMDN: Y122127

Basic UDI-DI: 897521376EWH01JH
Classification: Class I, According to Annex
 VIII, Regulation (EU) 2017/745

Declaration



Remark

The declaration of conformity is valid in connection
 with the release technical document
 CEMDR-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.

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

Signature:  Date: 24.4.19
 Position: GM Place: Xuzhou, Jiangsu, China

