



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Rep Name: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163
Münster, Germany
SRN:DE-AR-000000002

Manufacturer

Name: GUANGZHOU TOPMEDI CO.,LTD.
Address: RM1505-1507, GOLDEN SKY TOWER,
NO. 83, MIDDLE HUADI ROAD, 510380 LIWAN
DIST, GUANGZHOU, CHINA.
SRN: CN-MF-000016883

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 12184:2014
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021
EN ISO 13485:2016
MEDDEV 2.7.1 REV 4
IEC 62366-1: 2020
PMS
MDCG_2023-3_EN

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF01.

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

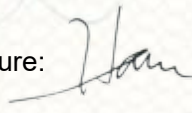
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: **POWERED WHEELCHAIR**
Model: **See ANNEX**
EMDN: **Y122127**
Basic UDI-DI: **697438762TPW001XE**
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.

Signature: 

Date: DEC. 16, 2024



Position: GM

Place: Guangzhou/China

Product Name	EMDN	Model
Powered Wheelchair	Y122127	<p>TEW007, TEW110A, TEW108LA, TEW139, TEW121LF1, TEW002, TEW118, TEW112G, THE158, THE148, TEW002G, TEW117, TEW005, TEW101A, TEW140, TEW008, TEW-CK05, TM-EW-015, TEW129, TEW101A, TEW101LAEF1, TEW102LAE, TEW105LAEK, TEW106LAEK, TEW107LAEF1, TEW108LAK, TEW110AK, TEW110LAEK, TEW110LAEF2, TEW110LAF1, TEW110LAF3, TEW110LF1, TEW111AF1, TEW112K, TEW121K, TEW121LF1, TEW122LGCK, TEW123K, TEW123F1, TEW123GCK, TEW124, TEW125GCK, TEW127K, TEW128K, TEW129K, TEW131GC, TEW101LAEF1, TEW102LAEF1, TEW102LAEF2, TEW102LAEF, TEW107LAE, TEW107LAEF, TEW108LAEK, TEW110AB, TEW110AF2, TEW110LABEFP2, TEW110LABF3, TEW110LF4, TEW111APF2, TEW112AF1, TEW123F2, TEW123GF3, TEW130LGC, TEW007F, TEW001, TEW110LA, TEW108LA (E), TEW112LAF1-46, TEW112LAF2-46, TEW110AE, TEW121LF1(afabM), TEW108LA(TLE), TEW108LA(E), TEW121LF1(M), TEW121LF1(B), TEW121LF1(afabTES), TEW118G, TEW007FG, TEW111, TEW007H, THE149, TEW002(E), TEW112E, TEW007G, TEW112LAF4, TEW111ABP, THE159, TEW002LA, TEW007S, TEW005(Lithium battery), TEW010, TEW005(Lead acid), TEW112, TEW007A, TEW806C, TEW105L(Lead acid), TEW105L(Lithium battery), TEW110LAE, TM-EW-028, TEW009, TEW123GC, TEW112AF1K, TEW101AK, TEW106LAE, TEW108LAE, TEW123F1K, TEW007D, TEW119, TEW138, TEW126, TEW002LAS, THE001, TEW121LF1K, TEW110LF1K, TEW110LAEF2K, THE967L, TEW007B+, TEW105LAE, TEW120AG, TEW110A(TE), TEW110A(TLE), TEW110A(LE), TEW110A(LE)-S, TEW110LABEFP3, TEW109, TEW104, TEW103, TEW006, TEW007N, TEW007D+, TEW007L, TEW007E, TEW108LABEJP, TEW108LABET, TEW108LABEF, TEW108LABEFP, TEW121LF1(afab), TEW121LF1(afabE), TEW112ABE, TEW112B, TEW112C, TEW112LAF3, TEW112LAE, TEW111AB, TEW110ABP, THE129F1, TEW002B, TEW020, TEW007DA, TEW007DS, TEW007DSA, TEW201, TEW202, TEW203, TEW204, TEW205, TEW206, TEW207, TEW208, TEW209, TEW210, TEW211, TEW212, TEW213, TEW214, TEW215, TEW216, TEW217, TEW218, TEW219, TEW220, TEW007T, TEW102L, TEW112E plus</p>