CE

DECLARAȚIE DE CONFORMITATE
CONFORM (UE) 2017/745 REGULAMENTUL PRIVIND DISPOZITIVELE MEDICALE

Reprezentant UE

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

Evaluarea Conformității

Procedura de evaluare a conformității
Anexa II+III din Regulamentul (UE) 2017/745

STANDARDE APLICABILE
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 12183:2014
EN ISO 13485:2016
MEDDEV 2.7 REV 4
IEC 62366-1: 2020
PMS
MDCG_2023-3_EN

Observație

Declarația de conformitate este valabilă în legătură cu documentul tehnic de lansare CE-MDR-TCF02.

Toată documentația justificativă este păstrată la sediul producătorului.

Declarația de Conformitate este exclusiv sub responsabilitatea producătorului.

Producător

Nume: GUANGZHOU TOPMEDI CO.,LTD.
Adresă: RM1505-1507, GOLDEN SKY TOWER,
NR. 83, MIDDLE HUADI ROAD, 510380 LIWAN
DIST, GUANGZHOU, CHINA.
SRN: CN-MF-000016883

Informații despre produs

Nume: Scaun rulant manual
Model: Vezi Anexa
EMDN: Y122103
UDI-DI de bază: 697438762TMW001WD
Clasificare: Clasa I, Conform Regulii 1, Anexa VIII, Regulamentul (UE) 2017/745

Declarație

Prin prezenta declarăm că produsele menționate mai sus îndeplinesc cerințele Regulamentului privind Dispozitivele Medicale (UE) 2017/745 și standardele aplicabile de mai sus.

Semnătură:

Semnătură indescifrabilă

Data: 6 dec. 2022

Funcție: GM

Locul: Guangzhou/China

Anexă

Model

TAW205LHQ, TAW251LHPQ,TAW250LCPQ, TAW253LACHQ, TAW218LQ, TAW959LQ, TAW957LQ, TAW955L, TAW950BEF1, TAW950LBPQ, TAW980LA, TAW952LCQ, TAW953LB, TAW208LAP, TAW207LABP, TAW908LJ, TAW907LABH, TAW903LQ, TAW874LJF5, TAW983L, TAW974LP, TAW864L, TAW874LAH, TAW864LAJ, TAW870LAJ, TAW869LJ, TAW878LAJ, TAW870LABJF5, TAW879LAJ, TAW872LAJ, TAW873LABJP, TAW868L, TAW871LBJ, TAW863LABJ, TAW805LABJ, TAW976LABJF2-43, TAW976LAB, TAW804LABJP, TAW800LBJ, TAW803LB, TAW807LABP, TAW980LA-30, TAW874LAJ-30, TAW980LA-35, TAW809L, TAW818LB, TAW001, TAW002, TAW003, TAW004, TAW005, TAW006, TAW007, TAW008, TAW009, TAW010, TLS737LQ-36, TLS734LQ-36, TLS731LQ-36, TLS730LQ-36, TLS732LQ-36, TLS727LQ-36, TLS720LQ-36, TLS723LQF1-36, TLS723LQ-36, TLS721LQ-36, TLS722LQ-36, TLS770LQ-32, TLS771LQ-32, TLS779LQ-36, TLS777LQ-36, TLS778LQ-36, TLS717L-30, TLS710L-30, TLS786LQ-36, TLS785LQ-36, TLS740LQ-36, TLS766LQ-36, TLS755LQ-36, TLS735LQ-36, TLS744LQ-43, TLS756LQ-36, TLS701, TLS702, TLS703, TLS704, TLS705, TLS706, TSW908AQ, TSW909, TSW909B, TSW902C, TSW901B, TSW901, TSW975-51, TSW907BC, TSW972BF2, TSW903, TSW904B, TSW972, TSW972B, TSW976ABJ-43, TSW951B-56, TSW209AE-61, TSW210ABE-61, TSW874F5, TSW870ABJ, TSW802-35, TSW810Y, TSW809, TSW809B, TSW874A, TSW874, TSW873, TSW869X, TSW875, TSW868, TEW-CK06, TRW258LBYGP, TRW958LBCGPY, TRW985LBGY, TRW954LGC, TRW203BJ, TRW204BJ, TRW212CEG, TRW801G, TRW954GC-46, TRW902GC-46, TRW901, TRW902, TRW903, TRW904, TRW905, TRW906, THE778LQ-36, THE779LQ-36, THE736LQ, THE255LPQ, THE004LGCP, THE958LBCGPY-38, THE974LAH-46, THE869LJP-43, THE874LAHP, THE018LPQ, THE870LAHP, THE976LA, THE203L, THE001, THE002, THE003, THE004, THE005, TAW800LF2, TRW958LBCGPYF9-38, TWA965LHF1, TAW903LAJPQF9, TAW908LQF19, TAW908LAJPF21, TAW863LAJPF8, TAW863LABJPF9, TAW208LABP, TAW869LABJX, TAW874LJPF10, TAW869LJX, THE974LA-35, TAW874LJPF7, TAW870LABJPF5, TSW909P-31, THE863LAJE, TLS727LQF1-36, TLS723LQF14-38, TLS730LQF10-36, TLS723LQF15, TAW808L,TAW811L,TAW812L,TAW813L,TAW814L,TAW815L,TAW816L,TAW817L,TAW819L,TAW820L,TSW971,TSW973,TSW974,TSW975,TSW977,TSW978,TSW979.TSW981,TSW982,TSW984,TSW985

TAW974LA-35, TAW958LBPYF8, TAW980LQF8, TAW863LAJPF4, TAW980LQF3-30, TAW863LABJPF1-30, TAW863LABJPF3, TAW863LAJPF7, TLS728LQ, TLS725LQ-41, TSW902C, TSW211BF1, TSW809F7, TSW808, TSW863AJPF1, TSW808J, TSW863ABJ, TSW863AJF1, TRW954LGCJF4, TRW203LBPY, TRW985LAF1, TRW954LGCF8, TRW908, TRW212BCEG, TSW868T, TSW701, TSW702, TSW803, TAW971LP, TAW818L, TAW903LAJQF9, TAW980LF3-35, TAW959LK01, TAW801LB, THE204L, TCM609LU, TCM697S, TCM695S, TCM619GC, TCM699L, TCM8831L, TCM692, TCM691, TCM694S, TCM609BU, TCM609GCJ, TCM6992L, TCM8835, TCM681, TCM683L, TCM691S, TCM609U, TCM609GCUF1, TCM693, TCM7964L-W5, TCM609LBU-52, TCM609LUF4, TCM692L, TCM698L-A, TCM6091, TCM6951S, TCM6952L, TCM6971S, TCM698L, TCM697S-1, TCM-060, TAW870LABJPF7, TAW806L, TAW865LJ, TAW206LABJ, TAW209LJ, TAW905L, TAW876L, TAW951L, TAW956L, TSW208, TSW207, TSW206, TSW801, TSW812, TSW973, TAW800LBF2, TAW903LPAF11, TAW205LPQF6-46, TSW301, TSW301F1, TSW301F2, TSW302, TSW302F1, TSW302F2, TAW976LF, TAW874LABJPM, TAW874LABJ, TAW874LAJP, TAW863LJF1, TAW863LJF2, TAW976LF2, TAW701LA, TAW702LAJ, TAW206LAJ, TAW800LBF3

*Subsemnatul **Narcis Antonese**, traducător autorizat cu nr. **6822/2002**, certific conformitatea traducerii în limba română cu textul înscrisului în limba engleză care a fost vizat de mine.*

Traducător autorizat,

NARCIS ANTONESE

