

Dichiarazione di conformità UE

Fabbricante:

Foshan Dongfang Medical Equipment
Manufactory (LTD.)

5 Xingfu Road, Zone A, Shishan Industrial Park,
Nanhai District, Foshan City, P.R. China, 528000

SRN: CN-MF-000036028

Relativo unico rappresentante autorizzato

MedNet EC-Rep GmbH

Borkstrasse 10, 48163 Muenster, Germany

SRN: DE-AR-000000002

In qualità di fabbricante, dichiariamo che i prodotti

FS SERIES MANUAL WHEELCHAIR

Modello: *Lista in allegato*

Nome commerciale: *MCM,EUROMIX,FS*

Codice UMDNS: **16949**

soddisfano le disposizioni del Regolamento sui dispositivi medici (UE) 2017/745 ad essi applicabili.

Il dispositivo medico è classificato come dispositivo di classe I secondo l'ALLEGATO VIII, regola 1 del Regolamento (UE) 2017/745. Porta il marchio



Procedura di valutazione della conformità: Allegato II, Allegato III del Regolamento (UE) 2017/745.

Standard applicati

BS EN 12183-2014 Manual wheelchairs. Requirements and test methods

BS ISO 10542-1-2012 Technical systems and aids for disabled or handicapped persons -- Wheelchair tiedown and occupant-restraint systems -- Part 1: Requirements and test methods for all systems

BS ISO 10542-2-2001 Technical systems and aids for disabled or handicapped persons - Wheelchair tiedown and occupant-restraint systems - Four-point strap-type tiedown systems

ISO 7176-1-2014 Wheelchairs - Determination of static stability; Identical with ISO 7176-1:1986

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ISO 7176-3-2012 Wheelchairs - Determination of efficiency of brakes; Identical with ISO 7176-3:1988

ISO 7176-5-2008 Wheelchairs - Determination of overall dimensions, mass and turning space; Identical with ISO 7176-5:1986

ISO 7176-7-1998 Wheelchairs - Part 7: Measurement of Seating and Wheel Dimensions First Edition

BS ISO 7176-8-2014 Wheelchairs - Requirements and test methods for static, impact and fatigue strengths

ISO 7176-11-2012 Wheelchairs - Part 11: Test dummies (ISO 7176-11:1992)

ISO 7176-13-1989 Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces First Edition; (CSA CAN/CSA-Z323.4.9- 94)

BS ISO 7176-15-1996 Wheelchairs - Requirements for information disclosure, documentation and labelling

BS ISO 7176-16-:2012 Wheelchairs - Resistance to ignition of upholstered parts - Requirements and test methods

BS ISO 7176-22-2014 Wheelchairs - Set-up procedures

DIN ISO 6440-1994 Wheelchairs - Nomenclature, terms and definitions; Identical with ISO 6440:1985

EN ISO 14971:2012 Application of risk management to medical devices

EN 980:2008 Symbols for use in the labelling of medical devices

EN 1041:2008 Information supplied by the manufacturer of medical devices

EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN 62366:2015 Medical devices - Application of usability engineering to medical devices

EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

La presente Dichiarazione di conformità è valida in combinazione con il documento di rilascio per il rispettivo lotto di dispositivi prodotti.

La suddetta dichiarazione di conformità è esclusivamente sotto la responsabilità di

Azienda: Foshan Dongfang Medical Equipment Manufactory (LTD.)

Indirizzo: 5 Xingfu Road, Zone A, Shishan Industrial Park, Nanhai District, Foshan City, P.R. China, 528000

佛山市东方医疗设备厂有限公司

FOSHAN DONGFANG MEDICAL

EQUIPMENT MANUFACTORY(LTD.)

CHINA Oct. 23, 2024

Luogo, data

Firma giuridicamente vincolante, Funzione

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MODELLO	BASIC UDI-DI
FS802-35	6938001010251
FS809	6938001010015
FS809B	6938001010725
FS809F7	6938001011760
FS810Y	6938001010053
FS863ABJ	6938001011005
FS863AJF1	6938001012095
FS863LAJPF1	6938001011098
FS868	6938001011173
FS869X	6938001011807
FS873	6938001010091
FS874	6938001010565
FS874A	6938001012101
FS874F5	6938001010688
FS875	6938001010312
FS901	6938001011883
FS901B	6938001011890
FS902C	6938001010237
FS902GC	6938001010596
FS903	6938001011906
FS903P-31	6938001012118
FS904B	6938001010527
FS907BC	6938001010701

FS908AQ	6938001011920
FS909	6938001010664
FS909B	6938001010732
FS951B	6938001010930
FS954GC	6938001010039
FS972	6938001010763
FS972B	6938001012019
FS975-51	6938001010244
FS976ABJ-43	6938001010268
FS203BJ	6938001011432
FS204BJ	6938001011449
FS209AE	6938001010572
FS210AB-61	6938001010619
FS211BF1	6938001011456
FS212BCEG	6938001010589
FS737LQ	6938001011647
FS740LQ	6938001012125
FS744LQ	6938001012132
FS755LQ	6938001011654
FS756LQ	6938001011661
FS766LQ	6938001011678
FS770LQ	6938001011685
FS771LQ	6938001011692
FS777LQ	6938001011708

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FS778LQ	6938001011715
FS779LQ	6938001011722
FS785LQ	6938001011739
FS786LQ	6938001011746
AU869LJP	6938001011357
AU870LAHP	6938001011364
AU874LAHP	6938001011371
AU958LBCGPY	6938001011388
AU974LAH	6938001011418
AU976LA	6938001011425
AU974LA	6938001011418
AU204L	6938001011319
FS203LBPY	6938001012149
FS205LHQ	6938001010350
FS207LABP	6938001011029
FS208LAPQ	6938001011012
FS208LABP	6938001012156
FS218LQ	6938001011463
FS250LCPQ	6938001011470
FS251LHPQ	6938001010367
FS253LACHQ	6938001011494
FS258LBYGP	6938001010459
FS723LQF14	6938001011555
FS723LQF15	6938001012163

FS730LQF10	6938001011593
FS800LBJ	6938001010060
FS803LB	6938001010282
FS804LABJP	6938001011067
FS805LABJ	6938001012170
FS807LABP	6938001011753
FS863LABJPF1-30	6938001012187
FS863LABJPF3	6938001011074
FS863LAJPF4	6938001011159
FS863LAJPF7	6938001011777
FS864L	6938001010022
FS868L	6938001011784
FS869LABJX	6938001012194
FS869LJ	6938001011791
FS863LAJPF8	6938001012200
FS863LAJPF9	6938001012217
FS869LJX	6938001011791
FS870LABJPF5	6938001010770
FS870LAJ	6938001011043
FS871LBJ	6938001011814
FS872LAJ	6938001011821
FS872LAJP	6938001012224
FS873LABJP	6938001011050
FS874LAJ-30	6938001011838

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FS874LJF5	6938001012231
FS874LJPF10	6938001011845
FS874LJPF7	6938001011852
FS907LABH	6938001010220
FS908LAJPF21	6938001011937
FS908LJ	6938001011944
FS908LQF19	6938001011951
FS950LBPQ	6938001011968
FS952LCQ	6938001012248
FS953LB	6938001011975
FS954LGC	6938001010336
FS954LGCF8	6938001010831
FS954LGCJF4	6938001011982
FS955L	6938001010329
FS957LQ	6938001011999
FS958LBCGPY	6938001010947
FS878LAJ	6938001011869
FS879LAJ	6938001011876
FS903LAJPQF9	6938001011913
FS903LQ	6938001011036
FS958LBPYF8	6938001012002
FS959LQ	6938001010343
FS971LP	6938001012255
FS976LAB	6938001012026

FS976LABJF2-43	6938001012033
FS980LA-30	6938001010848
FS980LA-35	6938001010190
FS980LA-46	6938001012262
FS980LQF3-30	6938001012040
FS980LQF8	6938001011142
FS983L	6938001012057
FS985LAF1	6938001012064
FS985LBGY	6938001010749

Prodotto		
Accessori	Rotella	6938001030068
	Set di rotelle	6938001030068
	Ruota	6938001030068
	Set di ruote	6938001030068
	Imbottitura del bracciolo	6938001030068
	set bracciolo	6938001030068
	Poggiapiedi	6938001030068
	Pedana	6938001030068
	Cuscinetto	6938001030068
	Barra di spinta	6938001030068
	Lock set	6938001030068
	Freno	6938001030068
	Set di freni	6938001030068
	Mozzo	6938001030068

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