

# EC Declaration of Conformity

*Manufacturer:*

Foshan Dongfang Medical Equipment  
Manufactory (LTD.)  
SRN:NOT YET

*whose single Authorized Representative:*

MedNet EC-Rep GmbH  
Borkstrasse 10. 48163 Muenster. Germany  
SRN:DE-AR-000000002

We, the manufacturer, herewith declare that the products

## **FS SERIES MANUAL WHEELCHAIR**

**Basic UDI(GMN):69380010005QR**

**Model:** *List in attachment*

*Trade Name:MCM,EUROMIX,FS*

*UMDNS-Code: 16949*

meet the provisions of Medical Device Regulation (EU)2017/745 which apply to them.

The medical device has been assigned to class I according to ANNEX VIII, rule1, Medical Device REGULATION (EU) 2017/745. It bears the mark



**Conformity assessment procedure:** Annex II, Annex III of EU 2017/745.

### **Applied standards**

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

BS ISO 10542-1:2012+A1:2021 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

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

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)

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

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

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

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ISO 7176-26:2007 Wheelchairs - Nomenclature, terms and definitions; Identical with ISO 6440:1985

EN ISO 14971:2019 Application of risk management to medical devices

EN ISO 155223-1:2016 Symbols for use in the labelling of medical devices

EN 1041:2008+A1:2013 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/A1:2020 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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Company: Foshan Dongfang Medical Equipment Manufactory (LTD.)**  
**Address: 5 Xingfu Road, Zone A, Shishan Industrial Park, Nanhai District, Foshan City,**  
**P.R. China, 528000**

FOSHAN DONGFANG MEDICAL  
EQUIPMENT MANUFACTORY(LTD.)  
  
.....  
AUTHORIZED SIGNATURE

FOSHAN, 2021-7-25

SUNNY LEANG, VICE MANAGER

*Place, date*

*Legally binding signature, Function*

Product		Model	Model	
Manual Wheelchair	Steel Wheelchair	FS802-35	FS903	
		FS809-46	FS903P-31	
		FS809B	FS904B	
		FS809F7	FS907BC	
		FS810Y	FS908AQ-46	
		FS863ABJ-46	FS909	
		FS863AJF1	FS909B	
		FS863LAJPF1	FS951B-56	
		FS868-46	FS954GC	
		FS869X	FS972	
		FS873	FS972B	
		FS874	FS975-51	
		FS874A	FS976ABJ-43	
		FS874F5	FS203BJ	
		FS875	FS204BJ	
		FS901	FS209AE-61	
		FS901B	FS210ABE-61	
		FS902C	FS211BF1	
		FS902GC	FS212BCEG	
			<a href="#">FS903F14-41</a>	
			<a href="#">FS863LAJPF4-46</a>	

Product		Model	Model		
Manual Wheelchair	Sport Wheelchair	FS710L-30	FS737LQ-36		
		FS717L-30	FS740LQ-36		
		FS720LQ-36	FS744LQ-43		
		FS721LQ-36	FS755LQ-36		
		FS722LQ-36	FS756LQ-36		
		FS723LQ-36	FS766LQ-36		
		FS723LQF1-36	FS770LQ-32		
		FS727LQ-36	FS771LQ-32		
		FS727LQF1-36	FS777LQ-36		
		FS730LQ-36	FS778LQ-36		
		FS731LQ-36	FS779LQ-36		
		FS732LQ-36	FS785LQ-36		
		FS734LQ-36	FS786LQ-36		
		FS735LQ-36			
		Manual Wheelchair	Auto	AU004LGCBJP	AU869LJP-43
				AU004LGCP	AU870LAHP
				AU018LPQ	AU874LAHP
				AU203L	AU958LBCGPY-38
AU255LPQ	AU974LAH-46				
AU736LQ	AU976LA				
AU778LQ-36	AU974LA-35				
AU779LQ-36	AU204L				

Product		Model	Model
Manual Wheelchair	Aluminum Wheelchair	FS203LBPY	FS874LAJ-30
		FS205LHQ	FS874LJF5
		FS207LABP	FS874LJPF10
		FS208LAPQ	FS874LJPF7
		FS208LABP	FS907LABH
		FS218LQ	FS908LAJPF21
		FS250LCPQ	FS908LJ
		FS251LHPQ	FS908LQF19
		FS253LACHQ	FS950BEF1
		FS258LBYGP	FS950LBPQ
		FS723LQF14-38	FS952LCQ
		FS723LQF15	FS953LB
		FS730LQF10-36	FS954LGC
		FS800LBJ	FS954LGC8
		FS803LB	FS954LGCJF4
		FS804LABJP	FS955L
		FS805LABJ	FS957LQ
		FS807LABP	FS958LBCGPY
		FS863LABJPF1-30	FS878LAJ
		FS863LABJPF3	FS879LAJ
		FS863LAJPF4	FS903LAJPF9
		FS863LAJPF7	FS903LQ
		FS864L	FS958LBPYF8
		FS868L	FS959LQ
		FS869LABJX	FS971LP
		FS869LJ	FS976LAB
		FS86LLAJPF8	FS976LABJF2-43
		FS863LAJPF9	FS980LA-30
		FS869LJX	FS980LA-35
		FS870LABJPF5	FS980LA-46
		FS870LAJ	FS980LQF3-30
		FS871LBJ	FS980LQF8
		FS872LAJ	FS983L
		FS872LAJP	FS985LAF1
		FS873LABJP	FS985LBGY
		<a href="#">FS903LPQF11</a>	<a href="#">FS958LBCGPYF9</a>
<a href="#">FS863LABJ</a>	<a href="#">FS950LB</a>		

Product		Model	Model
Accessories	Castor		
	Castor set		
	<a href="#">I.V POLE</a>	<a href="#">FS512</a>	
	<a href="#">TABLE</a>	<a href="#">FS561</a>	
	Wheel		
	Wheel set		
	Armrest Pad		
	Armrest set		
	Footrest		
	Footplate		
	Bearing		
	Push bar		
	Lock set		
	Brake		
<a href="#">SEAT</a>			
<a href="#">BACKREST</a>			
Brake set			
hub			

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