

EU Declaration of Conformity

Manufacturer:

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

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

SHOWER AND BATH BENCH, COMMODE AND ACCESSORIES

Model: List in attachment

Trade Name: MCM, EUROMIX, FS, SILFAB, FOSHAN

UMDNS-Code: 16005, 10788

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 : Annex II, Annex III of EU 2017/745.

Applied standards:

EN ISO13485:2016 Quality system-medical instruments

EN ISO 14971:2019 Risk analysis of medical instruments

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

EN ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing

EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-1:2020 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

BS 1254:1998 Specification for WC seats (plastics)

GB/T 24434-2009 Commode Chairs

Q/DF 6-2015 Bath bench - Enterprise Standard

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

佛山市东方医疗设备厂有限公司
FOSHAN DONGFANG MEDICAL
EQUIPMENT MANUFACTORY(LTD.)

Nov. 20. 2023.
Place, date

Legally binding signature, Function

EU Declaration of Conformity

E-Z-CE696.1-01, rev. A04 (DOC No., Revision)

Product	Model(s)
Shower and Bath bench	FS568S, FS569S, FS790, FS790B, FS791S, FS7921L, FS7931, FS7933S, FS793S, FS794L, FS794L-1, FS7954 FS7961L, FS7962L, FS7963L, FS7964L-W3, FS7992LU,FS7985LA,FS7982L.FS7991L,FS7981L,FS7986L,FS798L.FS796L,FS7987L,FS7971L,FS7972L,FS7985L, FS797L,FS7973L,FS7984LA,FS799L,
Commode	FS6091, FS609BU, FS609GCJ, FS609GCU, FS609GCUF1, FS609LU, FS609LBU-52, FS609LUF4, FS609U, FS619GC, FS654LVCU, FS681, FS683L, FS691, FS691S, FS692, FS693, FS694S, FS6951S, FS6952L, FS695S, FS696, FS6971S, FS697S, FS697S-1, FS698L, FS6992L, FS699L, FS7992L, FS8101, FS811, FS813, FS813(S), FS8133, FS813L, FS8831L, FS8832U, FS883L, FS890, FS892, FS8921, FS893, FS893L, FS894, FS8941, FS8943, FS894L, FS8951L, FS895L, FS8962, FS8964, FS897, FS897A, FS898, FS8992, FS8992-1, FS8992L, FS8995L, FS8996, FS8997, FS899-A,FS698L-A,FS7964L-W5,FS692L,FS8931,FS899U,FS696L,FS8945,FS8992L
Grab bar	FS7901B-L300, FS7901B-L400, FS7901B-L500, FS7902B-L400, FS7902B-L500, FS7902S, FS7903B, FS7904B FS7904S, FS7905SF1, FS7911S (12"), FS7911S (16"), FS7911S (24")
Accessoires	D107, D108, D109, D110, D111, D112, D113, D114, D115 (BED PAN AND URINAL series): FS665B, FS666B-100, FS666B-50, FS667B, FS668B, FS8141, FS8142

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MODEL	BASIC UDI-DI
FS568S	6938001020502
FS569S	6938001020519
FS790	6938001020625
FS790B	6938001021547
FS791S	6938001021554
FS7921L	6938001021561
FS7931	6938001021578
FS7933S	6938001021585
FS793S	6938001021592
FS794L	6938001021608
FS794L-1	6938001021615
FS7954	6938001021622
FS7961L	6938001021639
FS7962L	6938001020533
FS7963L	6938001021646
FS7964L-W3	6938001021653
FS7992LU	6938001021660
FS7985LA	6938001021677
FS7982L	6938001021684
FS7991L	6938001021691
FS7981L	6938001021707
FS7986L	6938001021714
FS798L	6938001020496
FS796L	6938001021127
FS7987L	6938001021721
FS7971L	6938001021738
FS7972L	6938001021745
FS7985L	6938001021752
FS797L	6938001020489
FS7973L	6938001021769
FS7984LA	6938001021776
FS799L	6938001020540
FS6091	6938001021806
FS609BU	6938001021813
FS609GCJ	6938001020892
FS609GCU	6938001021028
FS609GCUF1	6938001021820
FS609LU	6938001021837
FS609LBU-52	6938001021844
FS609LUF4	6938001021851
FS609U	6938001021035

MOEDL	BASIC UDI-DI
FS619GC	6938001020281
FS654LGCU	6938001021868
FS681	6938001020366
FS683L	6938001010633
FS691	6938001020373
FS691S	6938001020410
FS692	6938001020298
FS693	6938001020663
FS694S	6938001021875
FS6951S	6938001021882
FS6952L	6938001021899
FS695S	6938001020670
FS696	6938001020380
FS6971S	6938001021905
FS697S	6938001020649
FS697S-1	6938001021912
FS698L	6938001021929
FS6992L	6938001021936
FS699L	6938001020939
FS7992L	6938001021790
FS8101	6938001021943
FS811	6938001021950
FS813	6938001020816
FS813(S)	6938001021967
FS8133	6938001021974
FS813L	6938001021981
FS8831L	6938001021998
FS8832U	6938001022001
FS883L	6938001022018
FS890	6938001022025
FS892	6938001022032
FS8921	6938001022049
FS893	6938001020083
FS893L	6938001022056
FS894	6938001020021
FS8941	6938001022063
FS8943	6938001022070
FS894L	6938001020403
FS8951L	6938001022087
FS895L	6938001020748
FS8962	6938001020823

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MODEL	BASIC UDI-DI
FS8964	6938001022094
FS897	6938001020106
FS897A	6938001020656
FS898	6938001020113
FS8992	6938001021073
FS8992-1	6938001022100
FS8992L	6938001021059
FS8995L	6938001022117
FS8996	6938001022124
FS8997	6938001022131
FS899-A	6938001021066
FS698L-A	6938001022148
FS7964L-W5	6938001021783
FS692L	6938001022155
FS8931	6938001022162
FS899U	6938001021189
FS696L	6938001021288
FS8945	6938001022179
FS8992L	6938001021059
FS7901B-L300	6938001023084
FS7901B-L400	6938001023091
FS7901B-L500	6938001023107
FS7902B-L400	6938001023114
FS7902B-L500	6938001023121
FS7902S	6938001023138
FS7903B	6938001023145
FS7904B	6938001023152
FS7904S	6938001023169
FS7905SF1	6938001023176
FS7911S(12")	6938001023183
FS7911S(16")	6938001023190
FS7911S(24")	6938001023206
D107	6938001030075
D108	6938001030075
D109	6938001030075
D110	6938001030075
D111	6938001030075
D112	6938001030075
D113	6938001030075
D114	6938001030075
D115	6938001030075

MODEL	BASIC UDI-DI
FS665B	6938001030051
FS666B-100	6938001023251
FS666B-50	6938001023268
FS667B	6938001023275
FS668B	6938001023282
FS8141	6938001023299
FS8142	6938001023305

公司
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