

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

SHOWER AND BATH BENCH, COMMODE AND ACCESSORIES

Basic UDI(GMN):69380010002QK

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

FOSHAN DONGFANG MEDICAL
EQUIPMENT MANUFACTORY(LTD)



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AUTHORIZED SIGNATURE

FOSHAN, 2021-6-30

SUNNY LEANG, VICE MANAGER

EC Declaration of Conformity

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

Place, date

Legally binding signature, Function

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

