



中山市福佑康复器材有限公司

ZHONGSHAN BLISS MEDICAL INSTRUMENT CO., LTD

EU Declaration of Conformity

The following description for the medical device,

Device information	Description
Manufacturer Name and Address	Zhongshan Bliss Medical Instrument Co.,Ltd 2F-2, 3-6F & 7F-1, No.63, Tongxing East Road, Yumin Community, Xiaolan, Zhongshan City, Guangdong, 528414, China. Tel:+86-760-23630993
EU Single Registration Number (SRN):	CN-MF-000012262
EU Authorized representative	KOMAS Medical Technology GmbH Sternstraße 67, 40479 Düsseldorf, Deutschland
EU Single Registration Number (SRN):	DE-AR-000045617
Common device name	Hygiene Product
Registered trade name or trade mark	
Product series (models)	FBL620242,FBL610251,FBL650260 FBL650282,FBL650266,FBL620268 FBL630233,FBL610231,FBL620267 FBL900558,FBL640225,FBL710123
GMDN code	41069: Bath Back Rest/ Seat 31057: Basic Toilet Seat 31059: Raised Toilet Seat 40539: Commode 35584: Bath Hand-Hold Rail
Basic UDI-DI	Shower Chair: 697222054401FB Shower Chair: 69722254402FD Commode: 697222054301F6 Grab Bar: 697222054707G6 Toilet Safety Frame: 697222054708G8
Risk class of the device	Class I

That is covered by the present declaration is in conformity with the EU Medical Device **Regulation 2017/745/EU**. The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a general rule, under the

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sole responsibility for the above such devices. The class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 “EC declaration of conformity” after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1 set out in Annex VIII of the **Regulation**), the following harmonized standards are applied:

- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971:2019 Medical devices – Application of Risk Management*
- *EN ISO 15223-1:2021 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
- *EN 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*

The following person is exclusively responsible for the compliance of declaration:

Zhongshan Bliss Medical Instrument Co.,Ltd.

2F-2, 3-6F & 7F-1, No.63, Tongxing East Road, Yumin Community, Xiaolan , Zhongshan City, Guangdong, 528414, China.

(Manufacturer’s name/ Registered address)

John Mao / General Manager

June 5, 2025



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List of Comparison Table

Item No.	Description of Product	UDI-DI
FBL620242	Aluminum shower stool	6972220540922
FBL610251	Aluminum shower chair with backrest	6972220540649
FBL650260	Aluminum shower stool	6972220540939
FBL650282	Aluminum wall mounted shower stool	6972220540946
FBL650266	Aluminum wall mounted shower stool	6972220540953
FBL620268	Aluminum shower stool(Heavy duty)	6972220540960
FBL630233	Aluminum shower chair(Heavy duty)	6972220540977
FBL610231	Aluminum shower chair with backrest	6972220540984
FBL620267	Aluminum shower stool	6972220540991
FBL900558	Tub shower board	6972220541011
FBL640225	Aluminum shower stool	6972220541004
FBL710123	Commode chair	6972220541028

