



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	Walker/rollator
Registered trade name or trade mark	
Product series (models)	FBL855260,FBL855261,FBL855262 FBL855257,FBL855258,FBL855259
GMDN code	31118:Basic Walking frame,Non-Foldable 37961:Basic Walking Frame.Foldable 37951:Disability-Assistive Waler,Non-Powered,Foldable
Basic UDI-DI	Folding Walker:697222054101EU Riggid Walking Frame:697222054102EW Knee Walker:697222054103EY Rollator:69722205421EZ
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 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

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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)



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*John Mao / General Manager*

*June 5, 2025*



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List of Comparison Table

Item No.	Description of Product	UDI-DI
FBL855260	Rigid walking frame(Large)	6972220540212
FBL855261	Rigid walking frame(Medium)	6972220540182
FBL855262	Rigid walking frame(Small)	6972220540144
FBL855257	Rigid walking frame with wheels(Large)	6972220540199
FBL855258	Rigid walking frame with wheels(Medium)	6972220540175
FBL855259	Rigid walking frame with wheels(Small)	6972220540151

