



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	Cane/crutch
Registered trade name or trade mark	
Product series (models)	FBL507,FBL533,FBL534,FBL550120
GMDN code	31112: Single-base walking stick 31116: Multiple-base walking stick 45847: Walking stick/seat
Basic UDI-DI	Cane: 697222054501FG Walking stick: 697222054502FJ Quad cane:697222054503FL
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 of the **Regulation**.

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1

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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
BL533	Aluminum Swan Neck Big Base Quad Cane	6972220540908
BL534	Aluminum Swan Neck Small Base Quad Cane	6972220540892
FBL550120	Aluminum Quad cane	6972220540915

