

EC Declaration of Conformity

Manufacturer: Zhongshan Bliss Medical Instrument Co., Ltd

Address: No. 98, Zhaoyi Road, Dongsheng Town, Zhongshan, Guang Dong, 528414, China

EU Authorized Representative:

Company: Y. Sung Handelsvertretung

Address: Duesselthaler Str. 24, 40211 Duesseldorf Germany

DIMDI code: 0324700

Product name: Elbow Crutches

Model: see Annex.

UMDN code: 111063, crutches

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of (EU) MDR 2017/745

Conformity assessment route: ANNEX II + ANNEX III + Article 19 of (EU) MDR 2017/745

Intended Purpose: A walking aid to assist a person with a disability, to support their weight and provide stability, while walking

We hereby declare that the above-mentioned product meets the provision of the Medical Device Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.



EN ISO 13485:2016	EN ISO 14971:2012	
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	BS EN ISO 15223-1:2016

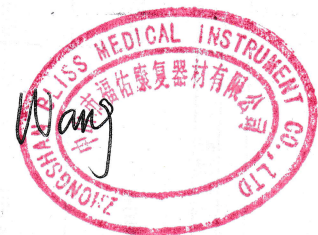
Basic UDI-DI	Elbow crutch:697222054603FR
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Place, Date of Issue:

Zhongshan, 29th Oct, 2021

Name: Emma Wang

Signature:



The signature is signed on behalf of Zhongshan Bliss Medical Instrument Co., Ltd

Annex: Model Designation:

Type	Model

Crutches

10403HD-30

10407R-30

10450-30

10451-30

10452-30

10453-30

10454-30