

EC CONFORMITY DECLARATION

Date and place of issue:25.04.2020

Conformity declaration issued by:

Commercial name	Zhangjiagang Braun Industry Co., Ltd.
Registered address	Buliding C7, No.199, Hongwu Avenue, Tangqiao Town, Zhangjiagang City, Suzhou City, Jiangsu Province, China
Reg.No.	320582000308946
Telephone	+86 512 58170517
Fax	+86 512 58170527

As the producer of the p	product-name	Hospital beds & Furniture (BiHealthcare)
Variantes of the product		Hosptial beds, transfer stretcher, mattress, bedside cabinet, over-bed table, chairs, medical cart and other furniture along with. (Variants are specified in the technical documentation of the product.)
Description and function designation		Hospital bed intended for patient lying and adjustable position for treatment. This EC conformity declaration also covers all applicable accessories approved by manufacturer.
classification of the product as the medical dvice:		Class I nonsterile, without measuring function, according to annex IX MDD 93/42/ECC-rule 12
Authorized Representative of	Company: SUNGO Cert GmbH Address: Harffstr 47, 40591 Dusseldorf, German	

Tel/Fax: +49(0)21197634133 | Email: ec.rep@sungogroup.com

European Union: A)Declaration

I declare that the said product is safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, sated in paragraph B.

B)Fulfilled technical requirements of related regulations

This product's characteristics comply with the technical parameters related to it and stated in MDD 93/42/EEC which stiplulates the technical parameters for healthcare products, with applicable specific requirements in directive 2006/42/EC which stipulates the technical parameters for machinery devices.

C)Means of assessing conformity

Conformity was assesssed by the procedure stated MDD 93/42/ECC, Annex VII.

D)Used standards for product conformity assessment

The said product fulfills the requirements of these harmonized technical standards which were used for assessing of conformity:EN 60601-1:2006/A1:2013.EN60601-2-52:2010.EN ISO 14971:2012.EN ISO

Zhonglin Wong Technical Director



