Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-6 din 14.07.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Grenoble 193
(adresa)
_____, tel./fax: 022768462, e-mail triumf.motiv@mail.ru,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Hospital Bed	BIH850EA
Hospital Bed	BIH008EA
Hospital Bed	BIH008EB
Hospital Bed	BIH0008EC
Hospital Bed	BIH008ED
Hospital Bed	BIH008EF
Hospital Bed	BIH001EA
Hospital Bed	BIH004EA
Hospital Bed	BIH500EA
Hospital Bed	BIH007EA
Hospital Bed	BIH007EB
Hospital Bed	BIH007EC
Hospital Bed	BIH007ED
Hospital Bed	BIH007EF
Hospital Bed	BIH010MA
Hospital Bed	BIH010MB
Hospital Bed	BIH010MC
Hospital Bed	BIH012MB
Hospital Bed	BIH012MK
Hospital Bed	BIH012MG

Digitally signed by Jighili Tatiana
Date: 2023.07.14 12:15:16 EEST
Reason: MoldSign Signature
Location: Moldova

Se anexează următoarele acte:
DECLAȚIE DE CONFORMITATE CE
CERTIFICATUL DE CONFORMITATE CE
Scrisoare de autorizare de la producător

Data 14.07.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: _____TRIUMF MOTIV SRL_____, cu sediul _____or. Chișinău str. Grenoble 193_____,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Hospital Bed	BIH850EA
Hospital Bed	BIH008EA
Hospital Bed	BIH008EB
Hospital Bed	BIH0008EC
Hospital Bed	BIH008ED
Hospital Bed	BIH008EF
Hospital Bed	BIH001EA
Hospital Bed	BIH004EA
Hospital Bed	BIH500EA
Hospital Bed	BIH007EA
Hospital Bed	BIH007EB
Hospital Bed	BIH007EC
Hospital Bed	BIH007ED
Hospital Bed	BIH007EF
Hospital Bed	BIH010MA
Hospital Bed	BIH010MB
Hospital Bed	BIH010MC
Hospital Bed	BIH012MB
Hospital Bed	BIH012MK
Hospital Bed	BIH012MG

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia Jighili Tatiana, Administrator
Semnătura _____

Data _14.07.2023___

ZHANGJIAGANG BRAUN INDUSTRY CO., LTD.
Tel: 0086-512-58170517
Fax: 0086-512-58170527
Buliding C7, No.199, Hongwu Avenue, Tangqiao Town,
Zhangjiagang City, Suzhou City, Jiangsu Province, China

Authorization Letter

16/06/2023

To whom it may concern,

We, the undersigned, **BiHealthcare (Zhangjiagang Braun Industry Co., Ltd)**, with address at **Buliding C7, No.199, Hongwu Avenue, Tangqiao Town, Zhangjiagang City, Suzhou City, Jiangsu Province, China**, hereby certify that the Company **Triumf Motiv SRL**, with address at **Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1,** is our distributor and importer of our range of Hospital beds & furniture, Operating table & light along with medical carts.

They have the complete ability and authority to participate in tenders, to bid, to negotiable, to sign contracts, to sell, to service and to apply for any necessary approvals and permissions on our behalf.

This statement is valid for 5 years from its date of signature.

张家港博舸科业医疗设备有限公司
ZHANGJIAGANG BRAUN INDUSTRY CO.,LTD.

Frank Lou
Sales Manager

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 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 European Union:	Company: SUNGO Cert GmbH Address: Harffstr 47, 40591 Dusseldorf, German Tel/Fax: +49(0)21197634133 | Email: ec.rep@sungogroup.com

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

张家港博朗科业医疗设备有限公司
ZHANGJIAGANG BRAUN INDUSTRY CO.,LTD.

CE

Certificate of EU Medical Device Notification

This is to certify that, according Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices,

Humiss Beratung GmbH
Address: Gneisenaustraße 8. 40477, Düesseldorf, Deutschland
TEL：+49-211-90760042; FAX：+49-211-90760043;
E-mail: eurep@humiss.com; Website: http://www.humiss.com
SRN: DE-AR-000023447

has fulfilled all notification responsibility and duty as the European Authorized representative of:

Manufacturer: Zhangjiagang Braun Industry Co., Ltd.
Address: Building C7, Hongwu Avenu, Tangqiao town, Zhangjiagnag City, Suzhou City, Jiangsu Province, 215600, China

The manufacturer has provided with all the appropriate declaration according the Regulation (EU) 2017/745 requirements including the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of Regulation (EU) 2017/745.

Product(s) details shown in the Annex of this certificate.

Where then manufacturer affixes the CE marking to the product listed, they must ensure that all the requirements of the appropriate EU regulation(s) have and continue to be met.

The notification of aforementioned device(s) has been completed by European Authorized representative in Germany, the Germany Competent Authority as flowing has notified the manufacturer's medical device above and has allocated registration.

Bezirksregierung Düsseldorf, Dezernat 24
Address: Cecilienallee 2, 40474, Düsseldorf, Deutschland
Tel: +49-211-4750, Fax: +49-211-4752671, E-mail: dez24.mpg@brd.nrw.de

This is only a CE mark sample which is only use for reference.

Humiss Beratung GmbH

Signature of Executive Director
James St. WU
Title: General manager

Cert. №: D-YQ-MD-230323066
Issue date: Mar.23, 2023
Valid until: Mar.22, 2028

Product name	Models	Activities	Registration number	Classification
Hospital bed	BIH850EA, BIH008EA, BIH008EB, BIH008EC, BIH008ED, BIH008EF, BIH001EA, BIH004EA, BIH500EA, BIH007EA, BIH007EB, BIH007EC, BIH007ED, BIH007EF, BIH010MA, BIH010MB, BIH010MC, BIH012MB, BIH012MK, BIH012MG	Manufacturer	DE/CA20/00192835	Class I, rule 13
Delivery table	BID001E, BID002H, BID007H, BID005E, BIPT825E	Manufacturer	DE/CA20/00192836	Class I, rule 13
Operating Table	BIOT900EH, BIOT800EH, BIOT600EX, BIOT600E, BIOT360EH, BIOT002EH, BIOT003M, BIOT004M, BIOT005EX, BIOT005E, BIHC100E	Manufacturer	DE/CA20/00192837	Class I, rule 13
Surgical light	BIOL800/600/C/M, BIOL800/800/C, BIOL800/600/C, BIOL800/C/M, BIOL800/800, BIOL800/600, BIOL600/600, BIOL720/720, BIOL800M. BIOL600M, BIOL720M, BIOL210, BIOL210W, BIOL150, BIOL150W	Manufacturer	DE/CA20/00192838	Class I, rule 13
Transport stretcher	BIPT585H, BIPT002H, BIPT003X, BIPT004E, BIPT012, BIPT006ST, BIPT300M	Manufacturer	DE/CA20/00192839	Class I, rule 13

Cert. №: D-YQ-MD-230323066
Issue date: Mar.23, 2023
Valid until: Mar.22, 2028