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-22 din 14.11.2023

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:

Denumire generică (denumirea dispozitivului)	Modelul
Centrifuge	2-6C

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

Data 14.11.2023 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	

Digitally signed by Jighili Tatiana
Date: 2023.11.14 16:29:55 EET
Reason: MoldSign Signature
Location: Moldova

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:

Denumire generică (denumirea dispozitivului)	Modelul
Centrifuge	2-6C

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia Jighili Tatiana, Administrator
Semnătura _____

Data _14.11.2023___

Digitally signed by Jighili Tatiana
Date: 2023.11.14 16:30:34 EET
Reason: MoldSign Signature
Location: Moldova

LETTER OF AUTHORIZATION

Date: June 10th, 2023

To Whom It May Concern:

Hereby, we

Company Name: Hunan Kecheng Instrument Equipment Co.,Ltd
Address: NO.602,6F,C2 Building, JinRong Wangcheng Sci-Tech Industrial Park,NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone , Changsha city,Hunan province,China
Phone number: +86-731-55881818

Certify that:

Triumf Motiv SRL
Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1
Phone number: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.
We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand Kecheng in your country.
This letter of authorization remains valid for five years, starting from June 20.2023 and expiring on March 09, 2028.

Name: Amy Liu

Title: Sales Director of Overseas Department

Signature: Amy Liu

HUNAN KECHENG INSTRUMENT EQUIPMENT CO.,LTD

Digitally signed by Jighili Tatiana
Date: 2023.11.14 16:30:07 EET
Reason: MoldSign Signature
Location: Moldova

KE CHENG

Hunan Kecheng Instrument Equipment Co.,Ltd

EC DECLARATION OF CONFORMITY

Manufacturer	:	Hunan Kecheng Instrument Equipment Co.,Ltd
Address	:	NO.602,6F,C2 Building, JinRong Wangcheng Sci-Tech Industrial Park,NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone , Changsha city.Hunan province,China
Product Name	:	Lab Centrifuge,Lab Grinder,Vacuum centrifugal concentrator
Model No.	:	2-6C， DT35C
Brand Name	:	Kecheng

We hereby confirm these products have already past all following standards:

EN 60204-1:2018
EN IEC 61000-6-2:2019
EN IEC 61000-6-4:2019
EN IEC 61000-3-2:2019/A1:2021
EN 61000-3-3:2013/A2:2021

related to CE Directive(s):
2014/35/EU (Low Voltage)
2014/30/EU (Electromagnetic Compatibility)

This document has been issued in accordance with the European Commission's note of 14 September 2022 ref. Ares (2022) 6342894 concerning voluntary certifications with a non-notified procedure

Place: GUANGZHOU Date:2023-1-24

Name: Amy Liu

Function: Manager

Signature: Amy Liu

(name and function of the signatory empowered to bind the manufacturer or his authorized representative)

HUNAN KECHENG INSTRUMENT EQUIPMENT CO.,LTD 湖南科成仪器设备有限公司

Address: NO.602,6F,C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone , Changsha city.Hunan province,China
Email:amy@kc-centrifuge.com Tel: +86-0731-55881818 Mob:+86-13974829066 Website:www.kc-centrifuge.com

Digitally signed by Ighili Tatiana
Date: 2023.11.14 16:30:19 EET
Reason: MoldSign Signature
Location: Moldova

Test Verification of Conformity

Certificate No.: CTSE21120026

Date: 2022-01-18

In accordance with the following Applicable Directives:

98/79/EC

In vitro diagnostic medical devices

The equipment, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of:

EN 61010-1: 2010+A1: 2019

EN 61010-2-101: 2017

The test results are traceable to the international or national standards.

Applicant: **Hunan Kecheng Instrument Equipment Co., Ltd**
NO.602, 6F, C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha city, Hunan province, China

Manufacturer: **Hunan Kecheng Instrument Equipment Co., Ltd**
NO.602, 6F, C2 Building, JinRong Wangcheng Sci-Tech Industrial Park, NO.858 Purui West Road, Wangcheng Economic & Technological Development Zone, Changsha city, Hunan province, China

EUT Name: **Centrifuge**

Model number: **GT116A**

Listed Model(s): GT216C,GT318C,GT320C,GT420C,GT116C,GTR216C,W3-16R,GTR318C,GTR320C GTR420C,4-25R,4-30R,GTR116C,GR16C,DT35C,DT36C,DT45C,DT46C,2-6C,2-5C DTR35C,DTR36C,DTR45C,DTR46C,GDR421C,GDR521C,GDR525C,GDR610C,RG16D DDR6C,DD6C,DDR72C,WK96C,TDL5Y, Super MiniStar, 2-4, Ministar, MiniStar Plus ES-6T, GT318A, DR5D, DR5, 4-5N, 5-5N, KC-48, KC-48R, L3-5KM, L4-5KM, TD4M H2-12K, TD4X, TD4K, TD4B, TD4K_v2, 3-5N, TD5B, L4-4F, ZL3, TD4, DR3C, GTR320A DT45A, DTR45A, GT420A, GTR420A, GDR421A, GDR521A , GTR318A, GT320A, 1-16 1-16R, 3-18, 3-18R, 3-20, 3-20R, 4-5, 4-5R, 4-20, 4-20R, 4-21R, 5-21R, GT116A, GTR116A 2-6A, DT35A, 7-72R, TD5Z, DDR72A, Minimax 17, ZL2E, ZL2F, ZL2G, ZL3-1K, ZL3-2K ZL3-3K, GDR610A, DDR5A, DD5A ,D3L,ZL3A

Laboratory:

Shenzhen Huatongwei International Inspection Co., Ltd.

1/F, Bldg 3 and Bldg 9, Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China

Tel: 86-755-26715499 E-mail: cs@szhtw.com.cn Website: Http://www.szhtw.com.cn

CE

Note:

The certification is only valid for the equipment and configuration described, in conjunction with the test data detailed above.

The CE mark as shown beside can be used, under the responsibility of the manufacturer, after completion of an EC Directive of Conformity and compliance with all relevant EC Directive.

For and on behalf of

Shenzhen Huatongwei International Inspection Co., Ltd.

Digitally signed by Jighili Tatiana
Date: 2023.11.14 16:31:52 EET
Reason: MoldSign Signature
Location: Moldova

Authorized by: Caroline Li

SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO., LTD. HTW