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. 1703-33 din 29.06.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, 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:

1. Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Se anexează următoarele acte:
1. Declaratia CE
2. Autorizație emisa de *Shenzhen Mindray Bio-Medical Electronics Co., Ltd., („Mindray")* pentru autorizarea *SRL Biosistem mld* sa inregistreze produsele *Beijing Mindray Medical Instrument Co., Ltd.* in Republica Moldova
3. Declaratie ca *Beijing Precil Instrument Co., Ltd.* apartine 100% la *Shenzhen Mindray Bio-Medical Electronics Co., Ltd., („Mindray")*
4. Declaratie ca *Beijing Precil Instrument Co., Ltd.* si-a schimbat denumirea in *Beijing Mindray Medical Instrument Co., Ltd.*
5. Declaratie pe propria raspundere
6. Lista dispozitivelor medicale solicitate spre notificare

Data 29.06.2023 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 Poiata Vitalie
Date: 2023.06.29 12:33:07 EEST
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: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, 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:

1. Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 29.06.2023

CIS-GJLA202212160015

December 15, 2022

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, **("Mindray")** manufacturer of Biochemistry, coagulation and hematology line of products**("Product(s)")** with principal place of business (legal address) Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized by the company mindray, to carry out the registration of products manufactured by Mindray in **Republic of Moldova ("Territory").**

This authorization is valid from the date of issuance to **December 31, 2023** and automatically renewable if no termination letter issued.

Best regards,

Duan Liang
General manager of Sales and Marketing Division, CIS I region
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com

Declaration of Conformity CE

Manufacturer: Beijing Precil Instrument Co., Ltd.
Room 203-204, 2F,Building 2,No.2, Tongji Middle Road, Beijing Economic & Technological Development Area, Beijing,100176,China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product: Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Model: LBY-XC20B、LBY-XC40、LBY-XC40B

Classification: Others(Not listed in the Annex II, Directive 98/79/EC)

Conformity assessment route: Annex III(Except 6), Directive 98/79/EC

We herewith declare that the above-mentioned products meet the previsions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.

Standard applied:
List of(harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2017-12-01

Place, Date: Beijing, 2017-12-01

Signature:
Name of Authorized Signatory: Zhang Yaohui
Position Held in Company: Management Representative

Applied Standards List

Product: Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Applied Standards:

EN 980:2008	Graphical symbols for use in the labeling of medical devices
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements IEC 61326-1:2005
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements IEC 61010-1:2001
EN 61010-2-081:2002 +A1:2003	Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC 61010-2-081:2001
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)
EN62304:2006	Medical device software-Software life-cycle processes

Drafted by: ____________

Checked by: ____________

mindray迈瑞
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, 12th Keji Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, P.R. China, 518057

December 28, 2017

Statement

To whom it may concern

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, with office at Mindray Building, Keji 12th Rd. South, Hi-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China, hereby declare that **Beijing Precil Instrument Co., Ltd.** with address at Room203-204, 2F, Building 2, No.2 Tongji Middle Road, Beijing 100176, P.R.China, is our wholly-owned China-based company as of December 2nd, 2016. Through **Shenzhen Mindray Equity Investment Funds Co., Ltd.** (**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** owns 99.9% of equity of **Shenzhen Mindray Equity Investment Funds Co., Ltd.**), we own 100% of equity of **Beijing Precil Instrument Co., Ltd.**.

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.

Shenzhen Mindray Bio-Medical Electronics Co., Ltd

20th June, 2022

Declaration

We, Beijing Mindray Medical Instrument Co., Ltd., to fulfill the need of improving the manufacturing capacity and maintaining the mid-long term development, hereby declares that the registered company name has been formally and officially changed to **"Beijing Mindray Medical Instrument Co., Ltd."** from "Beijing Precil Instrument Co., Ltd.", also the registered address has been changed to **"1F,2F,4F&5F, Building 3, No. 18 Science Park Road, Life Science Park, Changping District, Beijing 102206, China"** from "Room 203,204&401, Building 2, No.2 Tongji Middle Road, Beijing Economic & Technological Development Area, Beijing,100176, China".

The change of registration will accordingly affect the update of operation related files or information, which are including but not limited to:

- Company qualification certificate, including ISO13485, ISO9001 and other business licenses.
- Product registration certificate, including NMPA (China), CE (EU) and other medical product registration certificate.
- Product security certificate, including NRTL, CB, INMETRO etc.
- Product identification, including package labels, product labels, user manuals, and product brochures etc.
- Commercial documents, including Quotation, Proforma Invoice, Commercial Invoice, Bill of Lading.
- Third party documents, including FSC, Certificate of Origin.
- Others, including local purchase platform, custom registration, and other registered address related information.

We will duly update the above information upon the finish of official change of registration in compliance with relevant laws and regulations. The change period may vary in different countries or districts. Please be noted that before the completion of change of registered company name and address, there may inevitably exist differences or discrepancies between the registered company name and address in above information and official registered company name and address.

Therefore, Beijing Mindray Medical Instrument Co., Ltd. hereby declares that the change of registration will not in any manner affect the site of manufacture and operation, the operation process and the management requirement etc. and further declares that the products and services and the documents, records provided will not be affected by these changes.

Beijing Mindray Medical Instrument Co., Ltd.

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Monitor automat al vitezei de sedimentare a eritrocitelor (ESR).	Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor	LBY-XC20B	
2		Monitor automat al vitezei de sedimentare a eritrocitelor (ESR).	Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor	LBY-XC40	
3		Monitor automat al vitezei de sedimentare a eritrocitelor (ESR).	Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor	LBY-XC40B	