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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. **1908/24DM** din **19.08.2024**

Solicitant: **ÎM „DUTCHMED-M" SRL,** cu sediul

Str. Cetatea Alba 158, ap. 5, MD-2002, mun. Chișinău, Republica Moldova,

(adresa),

tel./fax: **022 522 022**, e-mail: **dutchmedm@gmail.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:

Sistem de supraveghere a perfuziei (stație de andocare pompe):
BeneFusion nDS, BeneFusion nDS ex, BeneFusion eDS, BeneFusion eDS ex

Se anexează următoarele acte:
1) Autorizație de reprezentanță emisă de producător (copie);
2) Certificatul de conformitate CE (copie);
3) Declarație de conformitate CE pentru Unitate de alimentare suspendate de tavan, emisă de producător (copie).

Data 19.08.2024 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	Accept ID 462100
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	nr 8911 din 19.08.2024
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Valentina Balgan
Semnătura persoanei responsabile	șef secție

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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. **1908/24DM** din **19.08.2024**

Solicitant: **ÎM „DUTCHMED-M" SRL,** cu sediul

Str. Cetatea Alba 158, ap. 5, MD-2002, mun. Chișinău, Republica Moldova,

(adresa),

tel./fax: **022 522 022**, e-mail: **dutchmedm@gmail.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:

Sistem de supraveghere a perfuziei (stație de andocare pompe):
BeneFusion nDS, BeneFusion nDS ex, BeneFusion eDS, BeneFusion eDS ex

Se anexează următoarele acte:
1) Autorizație de reprezentanță emisă de producător (copie);
2) Certificatul de conformitate CE (copie);
3) Declarație de conformitate CE pentru Unitate de alimentare suspendate de tavan, emisă de producător (copie).

Data 19.08.2024 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 deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **ÎM „DUTCHMED-M" SRL,** cu sediul

Str. Cetatea Alba 158, ap. 5, MD-2002, mun. Chişinău, Republica Moldova,

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

1) Autorizaţie de reprezentanţă emisă de producător (copie);
2) Certificatul de conformitate CE (copie);
3) Declaraţie de conformitate CE pentru Unitate de alimentare suspendate de tavan, emisă de producător (copie).

Sunt autentice şi corespund realităţii.

PRODAN Sveatoslav - Director
Numele, prenumele şi funcţia

Semnătura

Data ***19.08.2024***

Contract number: EC202408010017

AGREEMENT

(hereinafter referred to as Company A)

- SHENZHEN MINDRAY SCIENTIFIC CO., LTD
- 6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District, 518106 Shenzhen, P R.China

and

(hereinafter referred to as Company B)

- INTREPRINDEREA MIXTA „DUTCHMED-M" SOCIETATE CU RASPUNDERE LIMITATA
- 158, Cetatea Alba street, app. 5, Chisinau, MD2002, Moldova Republic of

Have agreed as follow, regarding the safe handling of the medical device (hereinafter called „Products") manufactured and supplied by Company A to Company B in order to comply with the requirements of the Government Decision HG702/2017 concerning Medical Devices (GDMD) and the „Guidelines on a Medical Devices Vigilance System"

APOINTMENT

Company A hereby appoints Company B upon the terms and conditions herein contained to be official representative for the products manufactured by Company A.

And whereas Company B expresses their desire to into an agreement with Company A upon the terms and conditions set forth in this Agreement.

RESPONSIBILITIES OF BOTH PARTIES – GENERAL INFORMATION

Company B is authorized to perform registration, renewal, variation of the registration.

Company A shall provide to Company B for the registration of medical devices the following information:

a) Declaration of conformity,
b) Copy of the label, packaging and instruction for use (in all languages requested by the countries where the device is marketed),
c) Notified Body certificates (where relevant),
d) Post market surveillance process and data, vigilance reports and complaints, processes and data,
e) Technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency (Agency),
f) Relevant clinical data/notification,
g) Details of any distributors/suppliers putting the Republic of Moldova marked devices on the market,
h) Incident reports and reports on corrective actions taken.

INTREPRINDEREA MIXTA S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA, mun. CHISINAU

Company B shall be responsible for registration, monitoring and to communicate all claims for the customers and market related of the products of Company A to notify Company B upon receiving such claims.

Incident Reporting

Company B shall maintain an update Quality System and communicate the vigilance procedures to Company A for coordination and continuity of Company A's own Quality System. Company B shall communicate any of other procedures upon request of the Company A.

Company B shall work closely with Company A and shall transmit without delay any information coming from the Agency. In case of special request by the Agency, particularly in relation with incidents reporting, the Company B will agree with Company A on the position statement and answers to give to the Agency.

A on the position statement and answers to give to the Agency.

In case of difference in positions between Company A and Company B, the position of Company A will prevail and b supplied to the Agency with a format endorsement of the Company A.

Company B shall have a qualified person to be in contact with the Agency.

In case of incidents known first by the Company A, the Company B will be immediately informed and will immediately perform with the Company A the analysis of the accident. The Company B will write and send to the concern Agency the initial report including Company A actions if available such as sample analysis, analysis of historic lot record and potential corrective actions to be taken in the further manipulation of the product like withdraw, recall from the market.

Company B shall notify Agency about the following time lines apply in a case of:

a) Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later that 2 calendar days after awareness by the company A of this threat.
b) Death or UNANTICIPATED serious deterioration is state of health: IMMEDIATELY (without any delay that could not be justified) after the company A established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.
c) Others: IMMEDIATELY (without any delay that could not be justified) after the company A established a link between the device and the event but no later than 30 elapsed calendar days following the date of awareness of the event.

If after becoming aware of a potential reportable, Company A must submit a report with the timeframe required for the type of INCIDENT.

As soon as information and incidents assessment from Company A are available, Company B writes and sends the final incidents report. In any case, Company B submits these reports to Company A for preliminary approval. Company B will keep these records available for the Agency.

According to the stipulation of medical equipment plan GDMD, the Company A must summarize the experience of manufacturing products, take proper measures, and have the right to know the incident occasionally happened, and take proper measures.

INTREPRINDEREA MIXTA S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA mun. CHIŞINĂU

a) The mangle of property of medical equipment, improper logo, and misuse without the guide of instruction for use can lead to the death of patient and users and deterioration of health condition.
b) The above-mentioned, the technical property of the products or the problems in medicine, the company has the recall the products of the products of the same lot and specification.

Field safety notice

The Company A finds that there is a problem of quality of the products on the market, it should immediately give out a Field Safety Notice for the users, so they could be able to take the necessary measures (including the recall of the products).

Recall

In case of products are withdrawn from the market, the Company A should recall the products immediately. Before recalling the products, the Company B should inform the Agency.

Return the products to the company

Company A shall send advisory notice to Company B in this region and order him to cease selling the products. Recall the products sold to the market or inform the users, ask the Company B in this region to inform the local governing department where the products are sold.

After the Company B recalls the products, Company A should agree with the Company B on the mode of transportation time, and return the products to the company for disposal.

Traceability of Sold Products

Company A shall keep records of serial numbers, batch numbers for all products delivered to Company B.

Company B shall keep records of the Products delivered to the users or distributors. In this case the traceability of sold products can be performed at any time upon request. Records shall include the following information:

Name and address of the customer

Quantity dispatched

Date transferred to the customer

Serial or production lot numbers

It is agreed that these records should be available for inspection upon request by Company A or by the relevant authorities.

Technical Documentation

Company A shell establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the products manufactured by Company A to be able to comply with the GDMD requirements.

ÎNTREPRINDEREA MIXTĂ S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA mun. CHIȘINĂU

Company A shall transfer the agreed Technical Documentation and Declaration of Conformity to Company B.

Company B shall keep the Technical Documentation and Declaration of Conformity available to the Agency for at least five years after the last products has been sold.

Company A shall provide to Company B and additional documentation if required by Agency.

Instruction Manual

Company A shall be responsible for content of instructions manual (user's guide) and shall ensure the availability of the English version of the instruction manual for Company B.

Company B shall ensure the requires instruction manuals to be provided to the customer in official language of the Republic of Moldova.

For the following Product Categories:

Patient Monitoring & Life Support

Product group and models/types:

1) Infusion System and their accessories

A: SHENZHEN MINDRAY SCIENTIFIC CO., LTD

2024.8.7

Name and Position place, date Signature

B: INTREPRINDEREA MIXTA „DUTCHMED-M" Societate CU RASPUNDERE LIMITATA

Rogan Sveatoslav Director Chisinau 29.04.2024

Name and Position place, date Signature

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 761396 R000

Manufacturer: Shenzhen Mindray Scientific Co., Ltd.

Address:
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block
Guangming District
Shenzhen
Guangdong
518106
China

Single Registration Number: CN-MF-000030037

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestraße 80
20537 Hamburg
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-01-03**

Current Issue Date: **2023-08-11**

Starting Validity Date: **2023-08-11**

Expiry Date: **2028-01-02**

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INTREPRINDEREA MIXTĂ S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA, mun. CHIȘINĂU

bsi.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 761396 R000

Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12– Administer and/or remove a medicinal substance	**Intended purpose**
Infusion pumps	The infusion pump is intended for use for the delivery of medications, solutions, nutrition, lipids, blood and blood components indicated for infusion therapy.
Syringe pumps	The syringe pump is intended for use on adults, paediatrics, and neonates for the intermittent or continuous delivery of medications, solutions, parenteral nutrition, lipids indicated for infusion therapy through an intravenous or intra-arterial routes.

Class IIb	**Intended purpose**
INFUSION AND SYRINGE PUMP CONTROL SYSTEMS	The device is intended for conjunction with the infusion pump and syringe pump, providing space management, power management, alarm management, information display, and communicate with pump to transmit data.

Device(s)	**Risk Classification**
Gravity infusion monitor	Class Im
Output monitor	Class Im
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

First Issue Date: **2023-01-03**

Current Issue Date: **2023-08-11**

Starting Validity Date: **2023-08-11**

Expiry Date: **2028-01-02**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 761396 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-03	3577341	Issued
2023-07-20	30002446	Supplemented - Addition of INFUSION AND SYRINGE PUMP CONTROL SYSTEMS.
Current	30005561	Supplemented - Addition of Gravity infusion monitor and Output monitor.

First Issue Date: **2023-01-03**

Current Issue Date: **2023-08-11**

Starting Validity Date: **2023-08-11**

Expiry Date: **2028-01-02**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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A Member of the BSI Group of Companies.

Declaration of Conformity V1.0

Declaration of Conformity

CE 2797

Manufacturer:	Shenzhen Mindray Scientific Co., Ltd. 6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District, Shenzhen, P. R. China
Manufacturer SRN:	CN-MF-000030037
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Infusion Supervision System
Model:	BeneFusion nDS, BeneFusion nDS ex BeneFusion eDS, BeneFusion eDS ex
Basic UDI-DI:	69469888AB01600029XN
Intended Purpose:	The Infusion Supervision System intended for conjunction with the infusion pump and syringe pump, providing space management, power management, alarm management, information display, and communicate with pump to transmit data.
Classification:	IIb (According to Rule 9 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	36179
MD code:	1111
MDR code:	MDA0306

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Notified Body No. :	2797
Identification of the Certificate:	**MDR 761396**
Start of CE-Marking:	**2020.5.23**

I hereby am appointed as the authorized person to deal with all the registration and quality

ÎNTREPRINDEREA MIXTĂ S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA, mun. CHIȘINĂU

management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Scientific Co., Ltd, Effective immediately.

Place, Date of Issue:	Shenzhen,
Signature:	Bai Yanhong 2024.05.27
Name of Authorized Signatory:	Ms. Bai Yanghong
Position Held in Company:	Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Infusion supervision system

Model: BeneFusion nDS, BeneFusion nDS ex
BeneFusion eDS, BeneFusion eDS ex

Standards Applied:

EN 60601-1:2006+A1:2013+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8 AMD2:2020	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015+AMD1:2020	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
IEC 62304:2015	Medical device software - Software life-cycle processes
IEC 60601-1-2:2014+AMD1:2020	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements

INTREPRINDEREA MIXTA S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA CHISINAU