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. 1 din 19.10.2023

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:

- Coopdech Qin Pot

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
Declaratie de conformitate
Scrisoare de imputernicire

Data 19.10.2023 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: 2023.10.19 14:57:29 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

DECLARAŢIE 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:

- Coopdech Qin Pot

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 19.10.2023

To: Whomever it may concern

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

05.10.2023

MANUFACTURERS AUTHORIZATION

We, Brandcom Ltd a company with its registered address at Romania,Iasi, Strada Silvestru 4, etaj 1 , office 1 , authorized distributor (representative) Daiken Medical Ltd Ja[an ., a company with its principal place of business located at 2-6-2, Ayumino, Izumi-city, Osaka, 594-1157, Japan ,hereby confirm that Biosistem mld SRL with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized by the company Brandcom Ltd , to carry out the registration of products manufactured by Daioken Medical Ltd ..in the Ministry of Health of Republic of Moldova.

This authorization is valid for 12 months from the date of issuance and automatically renewable if no termination letter issued.

BRANDCOM LTD
GENERAL; MANAGER
DR ALEXOAE GABRIEL

European Union Importer Agreement Under Medical Device Regulation (MDR 2017/745)

This European Union Importer Agreement is made between

Daiken Medical Co., Ltd., 2-6-2, Ayumino, Izumi-City, Osaka 594-1157, JAPAN, the Legal Manufacturer, hereinafter referred to as "DAIKEN", and BRANDCOM ROMANIA, IASI, Strada Silvestru , nr 4, etaj 1 , office 1 , the natural or legal person established within the European Union ( ), hereinafter referred to as "BRANDCOM" who places a device commercialized by the DAIKEN on the EU and former CSI markets. Details information of the Legal Manufacturer and the Importer is listed in Annex I.

For the purpose of this agreement a device shall be understood to be a medical device within the meaning of Article 2 point 1 or an accessory to a medical device within the meaning of Article 2 point 2 of the subject regulation.

1. Responsibilities of DAIKEN:

1.1. When placing their devices on the market or putting them into service, DAIKEN shall ensure that devices have been designed and manufactured in accordance with the requirements of MDR 2017/745.

1.2. DAIKEN shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I of MDR 2017/745.

1.3. DAIKEN shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV of MDR 2017/745, including a PMCF. Where applicable, DAIKEN shall provide a justification as to why a PMCF is not applicable in accordance with Annex III point 1.1 (b) of MDR 2017/745.

1.4. Other than custom-made devices, DAIKEN shall draw up and keep up to date technical documentation for devices placed on the market. The technical documentation shall be such as to allow the conformity of the device with the requirements of MDR 2017/745 to be assessed. The technical documentation shall include the elements set out in Annexes II and III of MDR 2017/745.

1.5. For custom-made devices, DAIKEN shall draw up, keep up to date and keep available for competent authority's documentation in accordance with Section 2 of Annex XIII of MDR 2017/745, where applicable.

1.6. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, DAIKEN as a manufacturer of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19 of MDR 2017/745, and affix the CE marking of conformity in accordance with Article 20 of MDR 2017/745.

1.7. DAIKEN shall comply with the obligations relating to the UDI system referred to in Article 27 of MDR 2017/745 and with the registration obligations referred to in Articles 29 and 31 of MDR 2017/745.

1.8. DAIKEN shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56 of MDR 2017/745, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Upon request by a competent authority, DAIKEN shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

DAIKEN shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3) of MDR 2017/745, ensure that the authorised representative has the necessary documentation permanently available.

1.9. DAIKEN shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or Common Specification (CS) by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner.

DAIKEN shall establish, document, implement, maintain, keep up to date and continually improve a quality management system in compliance with the requirements of Article 10 point 9 of MDR 2017/745.

1.10. DAIKEN shall implement and keep up to date the post-market surveillance system in accordance with Article 83 of MDR 2017/745.

1.11. DAIKEN shall ensure that the device is accompanied by the information set out in Section 23 of Annex I of MDR 2017/745 in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

1.12. If DAIKEN considers or has reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. DAIKEN shall inform the distributors of the device in question and, where applicable, the authorised representative and IMPORTER accordingly.

Where the device presents a serious risk, DAIKEN shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56 of MDR 2017/745, in particular, of the non-compliance and of any corrective action taken.

1.13. DAIKEN shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88 of MDR 2017/745.

1.14. DAIKEN shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned.

DAIKEN shall upon request competent authority of the Member State, provide samples of a device to competent authority of the Member State or allow competent authority access to the device.

DAIKEN shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

1.15. Where DAIKEN has their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1) of MDR 2017/745.

1.16. DAIKEN shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

1.17. DAIKEN shall, in accordance with the requirements of Articles 11 and 12 of MDR 2017/745, appoint a sole authorized representative within the European Union.

2. Responsibilities of the Importer:

2.1. IMPORTER shall place on the Union market only devices that are in conformity with MDR 2017/745.

2.2. In order to place a device on the market, IMPORTER shall verify that:

a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up.
b) DAIKEN is identified and that an authorized representative in accordance with Article 11 of MDR 2017/745 has been designated by DAIKEN.
c) the device is labelled in accordance with this regulation and accompanied by the required instructions for use.
d) where applicable, a UDI has been assigned by DAIKEN in accordance with Article 27 of MDR 2017/745.

Where IMPORTER considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, IMPORTER shall not place the device on the market until it has been brought into conformity and shall inform DAIKEN and DAIKEN's authorised representative.

Where IMPORTER considers or has reason to believe that the device presents a serious risk or is a falsified device, IMPORTER shall also inform the competent authority of the Member State in which IMPORTER is established.

2.3. IMPORTER shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by DAIKEN.

2.4. When available or on or before the date of application, IMPORTER shall verify that the device is registered in the electronic system in accordance with Article 29 of MDR 2017/745.

IMPORTER shall add their details to the registration in accordance with Article 31 of MDR 2017/745.

2.5. IMPORTER shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I of MDR 2017/745 and shall comply with the conditions set by DAIKEN, where available.

2.6. IMPORTER shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide DAIKEN, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.

2.7. IMPORTER who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform DAIKEN and its authorised representative.

IMPORTER shall co-operate with DAIKEN, DAIKEN's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken.

Where the device presents a serious risk, IMPORTER shall immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 of MDR 2017/745 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

2.8. IMPORTER who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to DAIKEN and its authorised representative.

2.9. IMPORTER shall, for the period referred to in Article 10(8) of MDR 2017/745, keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56 of MDR 2017/745.

2.10. IMPORTER shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market.

IMPORTER, upon request by a competent authority of the Member State in which the IMPORTER has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

2.11. IMPORTER shall assume the obligations incumbent on DAIKEN if IMPORTER does any of the following:

a) makes available on the market a device under IMPORTER name, registered trade name or registered trade mark,
b) changes the intended purpose of a device already placed on the market or put into service;
c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

2.12. For the purposes of 2.11 (c), the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

a) provision, including translation, of the information supplied by DAIKEN, in accordance with Section 23 of Annex I of MDR 2017/745, relating to a device already placed on the market

and of further information which is necessary in order to market the device in the relevant Member State;

b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

2.13. IMPORTER that carries out any of the activities mentioned in points (a) and (b) of 2.12 indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

IMPORTER shall shall notify DAIKEN and ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of 2.12 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy.

The quality management system shall cover, inter alia, procedures ensuring that the IMPORTER is informed of any corrective action taken by DAIKEN in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

2.14. At least 28 days prior to making a relabelled or repackaged device available on the market, IMPORTER carrying out any of the activities mentioned in points (a) and (b) of 12.2 shall inform DAIKEN and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide DAIKEN and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use.

Within the same period of 28 days, IMPORTER shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of 12.2, attesting that the quality management system of IMPORTER complies with the requirements laid down in 2.13.

3. Amendments to Agreement:

This agreement may be amended only by the written consent of both parties.

4. Term of Agreement:

This agreement shall commence on the date of the last signature and shall remain in effect for as long as the DAIKEN's medical devices are imported into the EU by IMPORTER or until such a time as a new agreement is signed. Furthermore, this agreement may be terminated at any time by either party so long as the intent to terminate is provided in writing to the other party.

SOCIETATEA COMERCIALA BRANDCOM

5. Resolution of Quality Issues:

DAIKEN and shall agree to work jointly to develop a strategy for resolution of quality issues. Both parties further agree to record such resolution in writing.

6. Signatures of Acceptance of the Agreement

Importer's Representative:

Signature:

Name:Dr. Alexoae Gabriel

Title:General Manager

Date: 10/09/2021

Legal Manufacturer's Representative:

Daiken Medical Co., Ltd.

Annex I

Legal Manufacturer

Name of Legal Manufacturer:	Daiken Medical Co., Ltd.
Address:	2-6-2, Ayumino, Izumi-city, Osaka, 594-1157, Japan
Main Tel No:	+81-725-30-3577
Main Fax No:	
Contact Name:	Kengo Wakita
Job Title:	Manager
Email:	wakita@daiken-iki.co.jp
Website:	http//www.daiken-iki.co.jp

AND

Legal Person Placing Medical Device on EU Market (Importer):

Importer Name:	**BRANDCOM**
Address:	Romania, Social Adress Iasi, Aleea Neculai Tudor, No 165, bl 1019, sc B,et 4, ap 17 PC 700713 Warehouse -Romania, Ilfov County, Chiajna ,Rosu, Apeductului Street no 14. PC 077040
Sale Territory	Austria, Romania
Main Tel No:	+40371137440
Main Fax No:	+40372872404
Contact Name:	Dr Alexoae Gabriel
Job Title:	General Manager
Email:	office@brandcom.ro
Website:	**www.brandcom.ro**

COOPDECH

CE01-K04-015

EC DECLARATION OF CONFORMITY

Manufacturer: DAIKEN MEDICAL CO., LTD.
2-6-2, Ayumino, Izumi-city, Osaka 594-1157, Japan

European Representative: Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80, D-66386 St. Ingbert, Germany

We, DAIKEN MEDICAL CO.LTD, do hereby declare that the medical devices, cited below, conform of the requirements of the Medical Devices Directive "93/42/EEC" and Annex 1.

Name: Coopdech Qin Pot
Product group: Canisters, Aspirator Collection (10-211)
Model(s)/Type(s): CQR10-Y-EU, CQR10-P-EU, CQR10-G-EU, CQR10-B-EU, CQR10-PY-EU, CQR10-PP-EU, CQR10-PG-EU, CQR10-PB-EU, CQR10-SY-EU, CQR10-SP-EU, CQR10-SG-EU, CQR10-SB-EU, CQR-Y-EU, CQR-P-EU, CQR-G-EU, CQR-B-EU, CQD10-H-EU, CQD10-G-EU
Accessories: Pipe Connector
Class: Class I (Annex IX Rule 1)
Applied approach: Annex VII of Medical Devices Directive "93/42/EEC"

Products covered：

Document Number	title	Number of products
F-EN03-01-00 (QP)	Quality Standard (Product Standard) (Model: QINPOT & QINPOT LINER)	Quality Standard (Product Standard)
SHJS-SB-001	Quality Standard (Product Standard)	Quality Standard (Product Standard)
QQD000-067	COOPDECH Qin Pot Quality records	each Lot Number

Lot Number:
Main Body: XXXXXX (six digits serial number)
Liner: XYYMMDDBZ (X: H (without solidifying agent) or G (with solidifying agent), YY-year, MM-month, DD-day, B-Batch No. if necessary, Z-specification if necessary)

This Declaration of conformity is valid in connection with the released document for the respective batch of produced device.

DAIKEN MEDICAL CO., LTD.,
2-6-2, Ayumino, Izumi-city, Osaka, 594-1157, Japan
TEL +81-725-51-2134 / FAX +81-725-54-0425

Standards applied:

EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO10079-3:2009	Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2016)
EN ISO 13485:2016/AC:2018	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 62366:2008	Medical devices – Application of usability engineering to medical devices(IEC 62366:2007)
MEDDEV2.7.1 Rev.3	Clinical Evaluation – A Guide for Manufacturers and Notified Bodies (December 2009)

Modification to the devices without prior approval from the undersigned will render this declaration null and void. This declaration of conformity and the "Technical Documentation" required by the directive will be on file at the manufacturer.

Place of declaration: DAIKEN MEDICAL CO., LTD.
2-6-2, Ayumino, Izumi-city, Osaka 594-1157, Japan

Date of declaration: 17 /Nov /2020

Signature:
(Authorized person)

Hiroaki Takimoto
Quality Assurance Manager

DAIKEN MEDICAL CO., LTD.,
2-6-2, Ayumino, Izumi-city, Osaka, 594-1157, Japan
TEL +81-725-51-2134 / FAX +81-725-54-0425