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. ..... din .....

Solicitantul **ANCOTEC-SISTEM SRL**, cu sediul mun. Chișinău, str. Cuza Vodă nr. 44, of 111, MD-2060, tel./fax: 079781169, e-mail achizitii@ancotec.md , 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:

- Microtom criostat cu set de cutite cito examinari al biopsiilor – model **6250 cryostat microtome**, producător Dakewe (Shenzhen) Medical Equipment Co LTD, Ţara de origine – China.

Se anexează următoarele acte:

Declarație de conformitate CE emisă de producător;
Certificat de conformtiate CE valabil pentru dispozitivele fabricate;
Autorizatie producator reprezentant autorizat;
Declarație pe propria răspundere privind veridicitatea datelor prezentate.

Data 28.08.2023

Semnătura

Digitally signed by Matei Andrei
Date: 2023.08.28 09:59:58 EEST
Reason: MoldSign Signature
Location: Moldova

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 Matei Andrei
Date: 2023.08.28 10:13:36 EEST
Reason: MoldSign Signature
Location: Moldova

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **ANCOTEC-SISTEM SRL**, cu sediul mun. Chișinău, str. Cuza Vodă nr. 44, of. 111, MD-2060, 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:

- Microtom criostat cu set de cutite cito examinari al biopsiilor – model **6250 cryostat microtome**, producător Dakewe (Shenzhen) Medical Equipment Co LTD, Ţara de origine – China.

Sunt autentice și corespund realității.

Digitally signed by Matei Andrei
Date: 2023.08.28 09:59:43 EEST
Reason: MoldSign Signature
Location: Moldova

Andrei MATEI *Semnătura* _____

Administrator Ancotec-Sistem SRL *Data 28.08.2023*

DAKEWE

MANUFACTURER'S AUTHORISATION

Date: 25th of August 2023

To: ***Medicines and Medical Devices Agency***

WHEREAS

We **Dakewe(Shenzhen) Medical Equipment Co., Ltd**, who are official manufacturer of quality pathology equipment, located at Floor 5, Building B, No.2 Luhui Road, Jinsha Community, Kengzi Street, Pingshan District, Shenzhen, China, do authorize **ANCOTEC-SISTEM SRL** with business office at 44 Cuza-Vodă str., Chișinău MD-2060, Republic of Moldova as our local authorized representative to submit the registration file to the Medicines and Medical Devices Agency and to register the following products in the State Register of Medical Devices, as follows:

- Cryostat Microtome- model 6250, manufacturer Dakewe(Shenzhen) Medical Equipment Co., Ltd, Country of origin - China;
- Rotary Microtome - model MT1, manufacturer Dakewe(Shenzhen) Medical Equipment Co., Ltd, Country of origin - China;

Signature and stamp: Liqin Guo

Dakewe (Shenzhen) medical equipment Co., Ltd 达科为(深圳)医疗设备有限公司

Name: Liqin Guo

Title: International commerial Supervisor

Date: August 25, 2023

Place: Shenzhen, China

Digitally signed by Matei Andrei
Date: 2023.08.28 09:59:30 EEST
Reason: MoldSign Signature
Location: Moldova

DAKEWE

EU DECLARATION OF CONFORMITY

We, **Dakewe (Shenzhen) Medical Equipment Co., Ltd.** (SRN:CN-MF-000009696), located at Floor 5, Building B, No.2 Luhui Road, Jinsha Community, Kengzi Street, Pingshan District, Shenzhen,China.

declare on our own responsibility, that the devices

Product	GMDN code	Basic UDI-DI
6250 cryostat microtome	15157	69711825707VW
The 6250 Cryostat Microtome is used for rapid freezing of pathological sections of human and animal body tissue.		

comply with

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

  IEC 61010-1:2010 IEC 61326-1:2020 ISO 14971:2019

  IEC 61010-2-101:2018 IEC 61326-2-6:2020 ISO 13485:2016

  Device classification: Class A

- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

  EN IEC 63000:2018

The device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

European representative:

SUNGO Europe B.V. (SRN: NL-AR-000000247)
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Signature: Tang Yuhao
Position: General manager
Date of issue: 2022.11.29
Place of issue: Floor 5, Building B, No.2 Luhui Road, Jinsha Community, Kengzi Street, Pingshan District, Shenzhen, China.

Digitally signed by Matei Aldrei
Date: 2023.08.28 10:00:19 EEST
Reason: MoldSign Signature
Location: Moldova

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20216811

Bijlagen
-

Uw aanvraag
18 november 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 6 december 2021
Betreft: notificatie In-vitro diagnostica

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 18 november 2021 van de notificatie van in-vitro diagnosticum dat bedrijf Dakewe (Shenzhen) Medical Equipment Co., Ltd., met Europees gemachtigde SUNGO Europe B.V., als fabrikant overeenkomstig Verordening (EU) 2017/746 (IVDR) op de markt wenst te gaan brengen.
De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Automatic Tissue Processor
(geen merknaam) (NL-CA002-2021-63301)
Cryostat Microtome
(geen merknaam) (NL-CA002-2021-63300)
Embedding Cassette
(geen merknaam) (NL-CA002-2021-63302)
Glass Coverslipper
(geen merknaam) (NL-CA002-2021-63299)
Slide Stainer
(geen merknaam) (NL-CA002-2021-63298)

Ik wijs u erop dat in-vitrodiagnostica die op de markt gebracht worden volgens de IVDR over een systeem voor hulpmiddelenindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de IVDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw producten overeenkomstig de huidige regelgeving hebt genotificeerd.

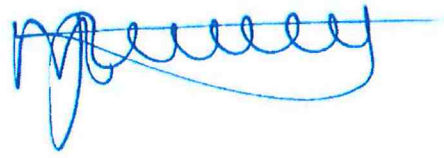
Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaande in-vitro diagnostica te registreren in Eudamed[3].

[1] O.g.v. art. 26 IVDR.
[2] O.g.v. art. 2 IVDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/EAG_IVDR_180117_V1.0-1.pdf, zie vraag en antwoord nummer 20.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw producten: notificering betekent niet dat daadwerkelijk sprake is van een in-vitrodiagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van *in-vitrodiagnosticum* valt.

De Staatssecretaris van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde