Digitally signed by Ionaşcu Andrei
Date: 2023.08.24 13:31:26 EEST
Reason: MoldSign Signature
Location: Moldova

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. ____ din _____ 2022

Solicitantul ”LifeMed Group” SRL, cu sediul or. com.Trușeni, str.Răzeșilor, 9, tel./fax 079511992,

079997471, e-mail lifemedgr@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:

Model	**Descriere**
GDC001EK3	Eprubetă pentru recoltarea sângelui capilar cu EDTA K3 (0.1ML)
GDC002EK3	Eprubetă pentru recoltarea sângelui capilar cu EDTA K3 (0.25ML)
GDC005EK3	Eprubetă pentru recoltarea sângelui capilar cu EDTA K3 (0.5ML)

Anexe
1. Declarații de conformitate
2. Certificat CE
3. Actul prin care producătorul își desemnează reprezentantul

Digitally signed by Iliev Ana
Date: 2023.08.23 18:07:50 EEST
Reason: MoldSign Signature
Location: Moldova

Data _____ 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	

ZheJiang GongDong Medical Technology Co.,ltd

ADD: No.10,Beiyuan Ave., Economic Development Zone,
Huangyan,Taizhou,Zhejiang,China,318020
TEL: 0086-576-84082907 **E-mail:** stephen@chinagongdong.com
FAX: 0086-576-84050789 **URL:** http://www.chinagongdong.com

Declaration

We, Zhejiang Gongdong Medical Technology Co., Ltd., based in No.10, Beiyuan Ave., Economic Development Zone, Huangyan, Taizhou, Zhejiang, China, 318020, assign “LifeMed Group” SRL, based in s. Trușeni, str. Răzeșilor, Republic of Moldova, as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is our distributor on the territory of the Republic of Moldova and is authorized to register, notify, renew or modify the registration of medical devices.

Place: Taizhou, Zhejiang, China , DATE: 2023/8/23

Signature:

Digitally signed by Iliev Ana
Date: 2023.08.23 18:06:09 EEST
Reason: MoldSign Signature
Location: Moldova

浙江拱东医疗器械股份有限公司
ZHEJIANG GONGDONG
MEDICAL TECHNOLOGY CO.,LTD.

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: "LifeMedGroup" SRL, cu sediul mun.Chisinau, com.Truseni, str.Razesilor, 9.

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 dispozitivelor medicale:

GDC001EK3	Eprubetă pentru recoltarea sângelui capilar cu EDTA K3 (0.1ML)
GDC002EK3	Eprubetă pentru recoltarea sângelui capilar cu EDTA K3 (0.25ML)
GDC005EK3	Eprubetă pentru recoltarea sângelui capilar cu EDTA K3 (0.5ML)

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Ana Iliev, director*

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Date: 2023.08.23 18:04:33 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Manufacturer:

Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000005694

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V11 042464 0039 Rev. 00

Report No.: SH2211102

Valid from: 2023-04-11

Valid until: 2028-04-10

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-04-11

Digitally signed by Iliev Ana
Date: 2023.08.23 18:13:43 EEST
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Classification:	Class A
Device Group:	W050101 - BLOOD COLLECTION DEVICES
Intended Purpose:	IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2023-04-11	SH2211102	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Zhejiang Gongdong Medical Technology Co.,Ltd.
No. 10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,
People's Republic of China.
http://www.chinagongdong.com

GONG拱东DONG

Declaration of Conformity

Manufacturer： Zhejiang Gongdong Medical Technology Co.,Ltd.
No.10,Beiyuan Ave., Economic Development Zone,Huangyan,
Taizhou,Zhejiang,China,318020

European Representative： Shanghai International Holding corp.GmbH(Europe)
Eiffestrabe 80 20537 Hamburg GERMANY

Product Name： Micro blood collection tubes

Model： No Additive (plain) and with additive

UMDNS Code： 16384

Classification (IVDD, Aneex III)： others

Conformity Assessment Route: IVDD

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Zhejiang Gongdong Medical Technology Co.,Ltd. is exclusively responsible for the DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standard Applied：

ENISO13485:2016；	EN ISO 15223-1-2016；	ENISO11607-1:2019
ENISO14971:2019；	ISO11135-1：2014；	EN 1041:2008+A1:2013；

(EC) Certificate(s)：Not applicable

Start of CE Marking：Not yet

Place, Date of Issue：HuangYan 2020-12-16

Signature：

Name： WeiFeng Zheng

Position： General Manager

ZHEJIANG GONGDONG MEDICAL TECHNOLOGY CO.,LTD. 浙江拱东医疗器械股份有限公司

Digitally signed by Iliev Ana
Date: 2023.08.23 18:07:06 EEST
Reason: MoldSign Signature
Location: Moldova