Anexă
Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. ..... din .....

Solicitantul **IM Vivamed International SRL**, cu sediul or. Chisinau,str.Mircea cel Batrin,16 (adresa)
tel./fax: 022926801, e-mail info@vivamed-int.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:

- Monitor Holter ECG (caracteristici avansate);
- Minitor pentru monitorizarea functiilor vitale
  (caracteristici avansate,accesorii Adult);

Se anexează următoarele acte
CE Certificat,
Declaratie de Conformitate,
Autorizatii de la producator.

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	

Digitally signed by Belan Irina
Date: 2023.07.02 16:16:21 EEST
Reason: MoldSign Signature
Location: Moldova

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:**IM Vivamed International SRL,** cu sediul in mun.Chisinau,Bd.Mircea cel Batrin,16,

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:

Monitor Holter ECG (caracteristici avansate);
Minitor pentru monitorizarea functiilor vitale (caracteristici avansate,accesori Adult)

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia
Director Beregoi Valeriu

Semnătura _____

Data _____

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Monitor Holter ECG (caracteristici avansate);	Creative Medical/Lepu Medical	TH 12	
2		Minitor pentru monitorizarea functiilor vitale	Creative Medical/Lepu Medical	K 15	

Director IM Vivamed International SRL
Beregoi Valeriu

Shenzhen Carewell Electronics Co., Ltd.
深圳市凯沃尔电子有限公司
地址：深圳市南山区西丽街道松白公路百旺信工业区 9 栋 4 层北侧
Add:Floor 4, BLD 9 Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street,
Nanshan District 518108 Shenzhen, P.R. China
Tel: +86-755-8617 0389, Fax: +86-755-8617 0478
Email:info@carewell.com.cn
http://www.carewell.com.cn

Authorization Letter

June 21st ,2023

We, Shenzhen Carewell Electronics Co., Ltd., having factoriesat Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110, Shenzhen, China.

hereby authorize

IM Vivamed Internationnal SL, with legal address in Str Bogdan Voievod 7MD-2068 Chişinău city Republic of Moldova, as our official distributor to promote, advertise, participate in tenders, sell and service the following products on the territory of Moldova:

PRODUCTS: Electrocardiograph/ Holter Recorder
BRAND: Carewell/ Lepu Medical
MODEL:ECG-1103G/ECG-1103L/ECG-1106L/ECG-1112M/TH12

The authorization remains valid for 1 years from Date: June 21th, 2023 to June 21th, 2024.

Shenzhen Carewell Electronics Co., Ltd.

SHENZHEN CREATIVE INDUSTRY CO., LTD.
Floor 5， BLD 9, BaiWangxin High-Tech Industrial Park,Songbai Road,Xili Street, Nanshan District,Shenzhen,China
Phone: +86 755 2643 3514 Fax: +86 755 2643 0930

Authorization Letter

June 21st ,2023

We, Shenzhen Creative Industry Co., Ltd., having factoriesat Floor 5， BLD 9, BaiWangxin High-Tech Industrial Park,Songbai Road,Xili Street, Nanshan District,Shenzhen,China

hereby authorize

IM Vivamed Internationnal SL, with legal address in Str Bogdan Voievod 7MD-2068 Chişinău city Republic of Moldova, as our official distributor to promote, advertise, participate in tenders, sell and service the following products on the territory of Moldova:

PRODUCTS: Patient Monitor
BRAND: Creative Medical/Lepu Medial
MODEL:UP-7000/K15

The authorization remains valid for 1 years from Date: June 21th, 2023 to June 21th, 2024.

Shenzhen Creative Industry Co., Ltd.

ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 049076 0016 Rev. 03

Manufacturer:

Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9
BaiWangxin High-Tech Industrial Park
Songbai Road, Xili Street
Nanshan District
518110 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry, Central Monitoring System**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 049076 0016 Rev. 03

Report No.: GZ2015303

Valid from: 2021-04-06
Valid until: 2024-05-26

Date, 2021-04-06

Christoph Dicks
Head of Certification/Notified Body

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®

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/EC)CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,
Songbai Road, Xili Street, Nanshan District,
518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE: Patient Monitor
MODEL:PC-3000/ Deluxe-70/ Classic-70/ UP-7000/Advance-120/ K10/K12/K15

CLASSIFICATION - ANNEX IX: Class IIb, Rule 10

GMDN CODE: 33586

CONFORMITY ASSESSMENTROUTE: Annex II excluding(4)

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICESMEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 (AMENDED BY DIRECTIVE 2007/47/EC) CONCERNING MEDICAL DEVICES;ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

ISO 13485: 2016	EN/ISO 14971: 2019	IEC 60601-1: 2005+A1: 2012
IEC 60601-1-2: 2014	IEC 60601-1-6: 2010+A1:2013	IEC 60601-1-8: 2006+A1: 2012
IEC 60601-2-49: 2018	IEC 60601-2-27: 2011	IEC80601-2-30: 2018
ISO 80601-2-61: 2017	ISO 80601-2-56: 2017	EN/ISO 15223-1: 2021
IEC 62304: 2006+A1: 2015	EN 1041: 2008+A1: 2013	ISO 10993-5: 2009
ISO 10993-10: 2010		

NOTIFIED BODY: TÜV SÜD Product Service GmbH .
Ridlerstraβe 65.80339 Munich.Germany

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1 049076 0016 Rev .03

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraβe 80, 20537 Hamburg, Germany

START OF CE-MARKING: OCT.15, 2010

PLACE, DATE OF DECLARATION: Shenzhen,May.21,2021

SIGNATURE:

SHENZHEN CREATIVE INDUSTRY CO.,LTD 深圳市科瑞康实业有限公司 中国·深圳 SHENZHEN CHINA

NAME: May.21,2021
POSITION: Management Representative

DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES

Name and Address of Manufacturer	Shenzhen Carewell Electronics Co., Ltd. Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Name and Address of European Representative	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard, 36, Heerenveen, Netherlands
Product Name/Model	Holter Recorder / TH3, TH12
GMDN code	36827
Classification	Class IIa , Rule 10 according to Annex IX of the MDD
Conformity Assessment Route	Annex II excluding Chapter 4
We, Shenzhen Carewell Electronics Co., Ltd., Ltd. here with declare that the above mentioned products meet the provisions of the Directive 93/42/EEC and following Standards. All supporting documents is remained at the premises of the manufacturer. EU Declaration of Conformity is issued under sole responsibility of the manufacturer.	
Standards Applied	EN 60601-1:2006+A1:2013+A2:2020, EN 60601-1-2: 2015+A1:2020, EN 60601-1-6:2010+A1:2015+A2:2020, EN 60601-2-47:2012, EN ISO 10993-1:2020, EN ISO 10993-5:2018, EN ISO 10993-10:2013, EN ISO 14971:2019, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020, EN ISO 15223-1:2021, EN 1041:2008+A1:2013, EN ISO 780: 2015
Name and Address of Notified Body	TUV SUD Product Service GMBH Ridlerstr 65, D-80339 Munchien.
Identification Number	0123
EC Certificate	G1 050440 0033 Rev.00
Place, Date of issue	Shenzhen, 2023.04.24
Signature	pan.Zhou SHENZHEN CAREWELL ELECTRONICS CO.,LTD. 深圳市凯沃尔电子有限公司 ※
Name and Position	Pan Zhou, management representative

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 050440 0033 Rev. 00

Manufacturer: **Shenzhen Carewell Electronics Co., Ltd.**
Floor 4, BLD 9
Baiwangxin High-Tech Industrial Park
Songbai Road, Xili Street
Nanshan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Infusion Pumps, Syringe Pumps, Electrocardiographs, AI-ECG Platform, AI-ECG Tracker, Holter Recorder**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 050440 0033 Rev. 00

Report No.: SH2026501

Valid from: 2021-01-19
Valid until: 2024-05-26

Date, 2021-01-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 050440 0034 Rev. 00

Manufacturer:	**Shenzhen Carewell Electronics Co., Ltd.** Floor 4, BLD 9 Baiwangxin High-Tech Industrial Park Songbai Road, Xili Street Nanshan District 518108 Shenzhen PEOPLE'S REPUBLIC OF CHINA
This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):	**G1 050440 0033 Rev. 00**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 050440 0034 Rev. 00

Report No.:	SH2226501
Valid until:	2024-05-26
Issue Date:	2023-04-18

Christoph Dicks
Head of Certification/Notified Body

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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 050440 0034 Rev. 00

Product Category(ies): Electrocardiographs, AI-ECG Platform,

AI-ECG Tracker, Holter Recorder

Description of Change:

Reduction of product categories – Products for Infusion pumps and Syringe Pumps
Old scope: Infusion Pumps, Syringe Pumps, Electrocardiographs, AI-ECG Platform, AI-ECG Tracker, Holter Recorder

New scope:
Electrocardiographs, AI-ECG Platform, AI-ECG Tracker, Holter Recorder

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

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Name and Address of Manufacturer	Shenzhen Carewell Electronics Co., Ltd. Floor 4, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Name and Address of European Representative	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard, 36, Heerenveen, Netherlands
Product Name/Model	Holter Recorder / TH3, TH12
GMDN code	36827
Classification	Class IIa，Rule 10 according to Annex IX of the MDD
Conformity Assessment Route	Annex II excluding Chapter 4
We, Shenzhen Carewell Electronics Co., Ltd., Ltd. here with declare that the above mentioned products meet the provisions of the Directive 93/42/EEC and following Standards. All supporting documents is remained at the premises of the manufacturer. EU Declaration of Conformity is issued under sole responsibility of the manufacturer.	
Standards Applied	EN 60601-1:2006+A1:2013+A2:2020, EN 60601-1-2: 2015+A1:2020, EN 60601-1-6:2010+A1:2015+A2:2020, EN 60601-2-47:2012, EN ISO 10993-1:2020, EN ISO 10993-5:2018, EN ISO 10993-10:2013, EN ISO 14971:2019, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020, EN ISO 15223-1:2021, EN 1041:2008+A1:2013, EN ISO 780: 2015
Name and Address of Notified Body	TUV SUD Product Service GMBH Ridlerstr 65, D-80339 Munchien.
Identification Number	0123
EC Certificate	G1 050440 0033 Rev.00
Place, Date of issue	Shenzhen, 2023.04.24
Signature	pan.Zhou SHENZHEN CAREWELL ELECTRONICS CO.,LTD. 深圳市凯沃尔电子有限公司 ※
Name and Position	Pan Zhou, management representative