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. 57 din 03.07.2023

Solicitantul „Neotec" SRL, cu sediul mun.Chisinau, str.Zaikin, 37, tel./fax: 022 852250/ 022 852252, e-mail office@neotec.md, agb@neotec.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:

1. Monitor pentru monitorizarea functiilor vitale K15

Se anexează următoarele acte:
1. Actul prin care producătorul își desemnează reprezentantul.
2. Declaratie pe proprie raspundere
3. EC Declaration Of Conformity
4. EC Certificat

Data 09.06.2023 Semnătura

Digitally signed by Botnaru Andrei
Date: 2023.06.28 13:29:23 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	

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: „Neotec" SRL, cu sediul in mun.Chisinau, str.Zaikin, 37,

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:

2. Monitor pentru monitorizarea functiilor vitale K15

Sunt autentice și corespund realității.

Botnaru Andrei- Director
Numele, prenumele şi funcţia *Semnătura* _____

Data 03.07.2023

Digitally signed by Botnaru Andrei
Date: 2023.06.28 13:30:59 EEST
Reason: MoldSign Signature
Location: Moldova

CREATIVE MEDICAL 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

MANUFACTURER'S AUTHORIZATION LETTER

25th. June, 2023

We, Shenzhen Creative Industry Co., Ltd. ,based in Floor 5， BLD 9, BaiWangxin High-Tech Industrial Park,Songbai Road,Xili Street, Nanshan District,Shenzhen,China , assign **Neotec SRL**, based in Str I. Zaikin 37 , Chisinau MD -2005, 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 authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Letter of Authorization shall remain in effect until 06/30/2024

Date: 25th, June, 2023

In the capacity of: **Shenzhen Creative Industry Co., Ltd.**

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

Digitally signed by Botnaru Andrei
Date: 2023.06.28 13:30:17 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EEC) 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:	K10, K12, K15
CLASSIFICATION - ANNEX IX:	Class IIb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex II .3

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 (AMENDED BY DIRECTIVE 2007/47/EEC) 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: 2012	IEC 60601-1: 2005+A1: 2012
IEC 60601-1-2: 2014	IEC 60601-1-6: 2010+A1:2013	EN 60601-1-8: 2007+A1: 2013
IEC 60601-2-49: 2011	IEC 60601-2-27: 2011	IEC 80601-2-30: 2009+A1: 2013
EN/ ISO 80601-2-61: 2017	EN/ISO 80601-2-56: 2017	ISO 80601-2-55: 2011
IEC 62304: 2006+A1: 2015	ISO 10993-1: 2009	ISO 10993-5: 2009
ISO 10993-10: 2010	EN/ISO 15233-1: 2012	EN 1041: 2008+A1: 2013

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 049076 0016 Rev .02
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:	Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, Apr. 20, 2019
SIGNATURE:	**NAME:** Apr. 20, 2019 **POSITION:** Management Representative

Digitally signed by Botnaru Andrei
Date: 2023.06.28 12:33:09 EEST
Reason: MoldSign Signature
Location: Moldova

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

TÜV SÜD 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)

G1 049076 0016 Rev. 02

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**

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. See also notes overleaf.

Report No.: GZ1915302

Valid from: 2020-01-07
Valid until: 2024-05-26

Digitally signed by Botnaru Andrei
Date: 2023.06.28 12:04:30 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2020-01-07

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

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

TÜV SÜD 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)

G1 049076 0016 Rev. 02

Facility(ies):

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

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

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TÜV®