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.____

Solicitantul Tetis International Co SRL, cu sediul str. Calea Orheiului 103/3, Chisinau,
(adresa)
tel./fax: (022) 44 50 65, e-mail farma@tetis.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:

- Dispozitive medicale conform listei:

Nr.	Modelul	Nr de catalog	Denumire
1	PRK-8000	-	Autorefractokeratometru
2	SIGMA F.O. LED ophthalmoscope 2.5V with rechargeable handle and battery - pouch - black	31582	Oftalmoscop direc
3	CHARGING STATION for Sigma oto-ophthalmo	31586	Incarcator oftalmoscop
4	HEINE OMEGA 600 LED	C-008.33.610 / 31755	Oftalmoscop indirect binocular
5	KS-H1N	30879	Lampă frontală

Se anexează următoarele acte:
a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;
c) actul prin care producătorul își desemnează reprezentantul.

Data 7.09.23 Semnătura _____

Tabelul de recepţionare 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 Vidiborschii Vladimir
Date: 2023.09.07 09:14:54 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

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant: Tetis International Co SRL, cu sediul str. Calea Orheiului 103/3, Chisinau,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

- Dispozitive medicale conform listei:

Nr.	Modelul	Nr de catalog	Denumire
1	PRK-8000	-	Autorefractokeratometru
2	SIGMA F.O. LED ophthalmoscope 2.5V with rechargeable handle and battery - pouch - black	31582	Oftalmoscop direc
3	CHARGING STATION for Sigma oto-ophthalmo	31586	Incarcator oftalmoscop
4	HEINE OMEGA 600 LED	C-008.33.610 / 31755	Oftalmoscop indirect binocular
5	KS-H1N	30879	Lampă frontală

Sunt autentice şi corespund realităţii.

7.09.23
Data

Semnătura

EC Declaration of Conformity

POTEC

The EC Directives covered by this Declaration

93/42/EEC (MDD) COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, amended by 2007/47/EC

Manufacturer: **POTEC Co., Ltd.**
40-4, Techno 2-ro, Yuseong-gu, Daejeon, 34015, Korea
(TEL: +82-42-632-3536 / FAX: +82-42-632-3537 / e-mail:webmaster@potec.biz)

EC Authorized Representative: **Medical Device Safety Service GmbH**
Schiffgraben 41, 30175 Hannover, Germany

The Product(s) Covered by this Declaration

Product description:	Auto Ref-Keratometers
Type designation(s):	PRK-5000, PRK-6000, PRK-7000, PRK-8000
MDD (93/42/EEC) Classification:	Class I with measuring function (Rule 12 of Annex IX)
Conformity Assessment Route:	Annex II w/o.4, 93/42/EEC
Start of CE Marking:	21.09.2005 (PRK-5000); 19.09.2008 (PRK-6000); 17.10.2013 (PRK-7000); 29.12.2016 (PRK-8000)

The Basis on which Conformity is being declared

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

- All applied harmonized standards were adopted under the EC Directive 93/42/EEC and published in the Official Journal of the European Communities

This Declaration of Conformity is based on the EC Directive 93/42/EEC, Annex II w/o.4 and supported by the TÜV NORD CERT GmbH (0044) certificate, with reference to articles 1 and 3 of the directive 93/42/EEC.

Notified Body:	TÜV NORD CERT GmbH Langemarckstraße 20, 45141 Essen, Germany
Identification No.:	0044
EC Certificate No.:	44 232 117847

We, Potec Co., Ltd., hereby declare under our sole responsibility that the above-mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC.

Valid of this Declaration: 13.12.2019 - 26.05.2024

Daejeon, 31.08.2020
Place, Date of Issue:

An-Soo Ko, President

TÜV NORD

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

POTEC Co., Ltd.
40-4, Techno 2-ro, Yuseong-gu
Daejeon 34015
Korea

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Automatische Ref-Keratometer
Auto Ref-Keratometers

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 44 232 117847
Bericht Nr. / *Report No.* 3525 3093

Gültigkeit / *Validity*
von / *from* 2019-12-13
bis / *until* 2024-05-26
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-12-13

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

REPUBLICA MOLDOVA, CHISINAU
fetis INTERNATIONAL CO
1003600043595
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

ANLAGE / *ANNEX*

Anlage 1, Blatt 1 von 1
Annex 1, page 1 of 1

Reg.-Nr. / *Reg. No.* 44 232 117847

Produkte der Klasse Im *Products of class Im*	Typ *Type*	UMDNS
Ref-Keratometer, automatische ***Auto-Ref-Keratometer***	**PRK-5000** **PRK-6000** **PRK-7000** **PRK-8000**	**13-313 + 12-811**

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.
Note: For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Bericht Nr. / *Report No.* 3525 3093

Gültigkeit / *Validity*
von / *from* 2019-12-13
Edition 6

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-12-13

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Shantou Easywell Electronic Technologies Co.,Ltd NO.1 West side of 6th Floor H5 Industrial Building, No. 16 Lianjiang Road,Longhu district,Shantou,China(515041)
Trademark:	Easywell
European Representative:	Kingsmead Service B.V. Zonnehof 36, 2632 BE, Nootdorp, Netherland
SRN	NL-AR-000002066
Trade name:	Medical lights
Product name:	Medical lights
Product code / Catalogue number:	KS Series, MST Series, SL Series, LED Series
Basic UDI	697447153000L4 / 697447153001L6/ 697447153004LC
Classification acc. to MDR Ax. VIII:	Class I, rule 13
Applied Standard & Common Specification:	EN ISO14971:2012 , EN1041:2008, EN60601-1:2006+A1:2013, EN60601-1-2:2015, EN60601-2-41:2009
Conformity assessment procedure:	Annex II + Annex III of MDR

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices(MDR). All supporting documentations are retained under the premises of the manufacturer.

SHANTOU EASYWELL ELECTRONIC TECHNOLOGIES CO., LTD. 汕头市维电子科技有限公司 0754 2303030

Justin Liu
General Manager

Shantou City, Guangdong Province, China 10. 03. 2021

EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6, 82205 Gilching, Germany
www.heine.com

Single Registration Number: DE-MF-000006269

INDIRECT OPHTHALMOSCOPES

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The indirect ophthalmoscopes consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
OMEGA 600	4053755_IO_01_5Z	46790	12-818
OMEGA 600 wired			
OMEGA 500 LED			
OMEGA 500			
SIGMA 250			
SIGMA 250 M2			
Indirect Ophthalmoscope MONOCULAR	4053755_HHIO_01_Q9	46788	12-818
Indirect Ophthalmoscope BINOCULAR		46790	

and

mPack	4053755_PP_01_97	--	16-337
mPack UNPLUGGED			
mPack mini			
BETA battery handle	4053755_BH_01_YN		
BETA SLIM battery handle			
Large battery handle			
BETA 4 USB rechargeable handle	4053755_RH_01_79		
BETA 4 NT rechargeable handle			
BETA 4 SLIM NT rechargeable handle			
BETA NT rechargeable handle			
BETA L rechargeable handle			
BETA SLIM NT rechargeable handle			
EN 200 wall transformer	4053755_WT_01_DE	16933	16-935
EN 200-1 wall transformer			

The indirect ophthalmoscopes are class I according to the risk classification of Annex VIII.

CE

References to any common specifications: N/A
This declaration of conformity is valid until a revised declaration of conformity is issued.

Gilching, 20 January 2022
(Place and date of Issue)

Thomas Sauerer / PRRC
(Name/function and signature)

HEINE OPTOTECHNIK
GmbH & Co. KG
Dornierstr. 6
82205 Gilching

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
SIGMA F.O. LED OPHTHALMOSCOPE 2.5V with rechargeable handle and battery - pouch - black	31582	8023279Z121201140000000Q9

Risk class I (Not sterile), according to the Rule 13 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;
- comply with directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

Medical Device (Trade Name and description)	Code	Basic UDI-DI code
CHARGING STATION for Sigma oto-ophthalmo	31586	8023279Z120210800700000UJ

Risk class I (Not sterile), according to the Rule 13 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;
- comply with directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)

beurer
GESUNDHEIT UND WOHLBEFINDEN

Förderndes Mitglied der
Deutschen Hochdruckliga
Förderndes Mitglied der
Deutschen Diabetes Stiftung

EC - Declaration of Conformity

Document no.:	BY80_CE_DoC
Manufacturer:	Beurer GmbH
Address:	Söflinger Strasse 218, 89077 Ulm, Germany
Product:	Baby Scale
Type:	BY80

This declaration of conformity is issued under the sole responsibility of the manufacturer. The designated product conforms to the provisions of the following European Directives, Commission Regulations and harmonised standards:

2014 / 30 / EU	Electromagnetic Compatibility (EMC) EN 55014-1: 2006 + A1: 2009 + A2: 2011 EN 55014-2: 1997 + A1: 2001 + A2: 2008
2011 / 65 / EU	Restriction of the use of certain hazardous substances (RoHS)

Affixing of the CE – mark:	2014
Issuer:	Werner Meternek
Position:	Director Research & Development
Place, date:	Ulm, 23.06.2016
Legally binding signature:	i.A. Beurer GmbH Söflinger Straße 218 • 89077 Ulm

BEURER GmbH · Postfach 1427 · D-89004 Ulm · Hausanschrift: Söflinger Strasse 218 · D-89077 Ulm · Tel. 0731/3989-0 · Fax 0731/3989-139 · kd@beurer.de · www.beurer.com
USt-IdNr.: DE147040787 · Sitz der Gesellschaft: Ulm · Amtsgericht Ulm HRB 722213 · Aufsichtsratsvorsitzender: Martin Bertinchamp · Geschäftsführer: M. Bühler, M. Holmeister, G. Walkenbach
Banken: Commerzbank Ulm BIC: COBADEFF630 IBAN: DE11 6304 0053 0920 1013 00 · Baden-W. Bank Ulm BIC: SOLADEST IBAN: DE35 6005 0101 7439 5020 17
Sparkasse Ulm BIC: SOLADES1ULM IBAN: DE57 6305 0000 0006 5048 30 · Volksbank Ulm-Biberach BIC: ULMVDE66XXX IBAN: DE73 6309 0100 0001 0230 04