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.____

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	Catalog	Denumire
1	OTOPEX	OTOPEX ENT CHAIR with headrest - green Toronto	Fotoliu multifuncțional ORL
2	PRK-7000	PRK-7000	Autorefracto-keratometru
3	MINISPIR	MINISPIR	Spirometru
4	BF LED 50.2	BF LED 50.2	Negatoscop
5	MI370X	PROFESSIONAL EXAMINATION COUCHES – LYTUS	Canapea de examinare
6	OTOP/V ELEGANCE	NEW OTO/PV ENT CHAIR with headrest - green Melbourne	Fotoliu multifuncțional ORL
7	30939	"P16" NEW GIMA LED HEAD LIGHT	Lampa de frunte ORL

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 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 Vidiborschi Vladimir
Date: 2023.06.11 13:37:28 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: 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 și datele furnizate pentru notificarea dispozitivului medical:

- Dispozitive medicale conform listei:

Nr.	Modelul	Catalog	Denumire
1	OTOPEX	OTOPEX ENT CHAIR with headrest - green Toronto	Fotoliu multifuncțional ORL
2	PRK-7000	PRK-7000	Autorefracto-keratometru
3	MINISPIR	MINISPIR	Spirometru
4	BF LED 50.2	BF LED 50.2	Negatoscop
5	MI370X	PROFESSIONAL EXAMINATION COUCHES – LYTUS	Canapea de examinare
6	OTOP/V ELEGANCE	NEW OTO/PV ENT CHAIR with headrest - green Melbourne	Fotoliu multifuncțional ORL
7	30939	"P16" NEW GIMA LED HEAD LIGHT	Lampa de frunte ORL

Sunt autentice și corespund realității.

_____

Numele, prenumele şi funcţia

Data *Semnătura* _____

Dichiarazione di Conformità

(ai sensi dell'articolo 19 del Regolamento Europeo (UE) 745/2017)

Declaration of Conformity

(according to Article 19 of the European Regulation (EU) 2017/745)

La società / *The company* **MEDI-CARE SOLUTIONS s.r.l.**
Sede legale/*Legal office*: Via Della Zecca N° 1 - 40121 Bologna (BO) Italy
Sede operativa/*Facility*: Via Pietro Nenni 3 - 40026 Imola (BO)- Italy
Tel. ++39 0542 642046 Fax ++39 0542 642355 – Mail: info@euroclinic.it

in qualità di fabbricante dei seguenti dispositivi medici, che vengono immessi in commercio a proprio nome, dichiara sotto la propria esclusiva responsabilità, che il seguente prodotto destinato alla visita e al trattamento in ambito Otorinolaringoiatrico/*as manufacturer of the following MD, which is marketed in its own name, declares under his responsibility, that the following product intended for examination and treatment in the ENT field:*

Denominazione/Modello *Denomination/Model*	**Classificazione, Regola*** *Classification, Rule**	**Numero identificazione (S/N)** *Serial Number*	**UDI-DI** *UDI-DI*
OTOPEX	**I, Regola 1 e Regola 13** **Class I, Rules 1 and 13**		Non disponibile *Not available*

* secondo l'Allegato VIII Regolamento Europeo (UE) 745/2017
** according to Annex VIII European Regulation (EU) 2017/745*

È conforme ai requisiti essenziali richiesti dall'allegato I del Regolamento Europeo (UE) 745/2017 ed alle seguenti Specifiche Comuni (SC):

- Nessuna applicabile al prodotto

Qualunque modifica apportata ai suddetti dispositivi se non autorizzata da Medi-Care Solutions S.r.l. annulla la validità della presente dichiarazione.

Si dichiara che il fabbricante ha notificato all'autorità competente i suddetti Dispositivi Medici e, in seguito alla immissione in commercio degli stessi, applica specifica procedura di sorveglianza post-vendita dei prodotti come richiesto dal Regolamento Europeo (UE) 745/2017 (articolo 83).

Si dichiara infine che la scrivente terrà a disposizione delle Autorità Sanitarie la documentazione tecnica realizzata ai sensi dell'allegato II e III del Regolamento Europeo (UE) 745/2017 per un periodo di almeno 10 anni a partire dall'ultima data di produzione dei dispositivi in oggetto.

La presente dichiarazione di conformità ha validità 10 anni.

It complies with the essential requirements of Annex I of the European Regulation (EU) 2017/745 and with the following Common Specifications (CS):

- *None applicable to the product*

Every modification applied to the aforementioned devices, without previous Medi-Care Solutions S.r.l authorization, invalidate the present declaration.
The manufacturer declares that has notified to the competent authorities the aforementioned devices and, after placing them in the market, it applies the specific product after-sales surveillance procedure as required by Article 83 European Regulation (EU) 2017/745.
Finally, the manufacturer will keep available the technical documentations at the disposal of the European and National Health Authorities for a period of at least 10 years from the last day of production of the aforementioned devices.
The present declaration of conformity is valid for 10 years.

Direzione Generale
Medi-Care Solutions srl
(Per conto del Presidente del CdA, Sig. Benedetto Uberto Selvatico Estense)

Imola (BO), 28/07/2021

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):

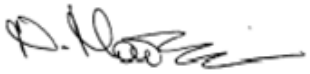
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
"P16" NEW GIMA LED HEAD LIGHT	30939	802327900Z129004B400000R2

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, 04/07/2022

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



MORETTI

MORETTI S.p.A.
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Fax. + 39 055 96 21 200
www.morettispa.com
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Part. IVA 00306090515
Meccanografico AR 005370
Reg. Imp. Arezzo 00306090515

R.E.A. Arezzo 68869
Cap. Soc. € 1.500.000,00
C/C Postale 13682521

DICHIARAZIONE DI CONFORMITA' UE

CE

Regolamento UE 2017/745

MORETTI S.p.A.

SRN: *IT-MF-000005980*

dichiara sotto la sua esclusiva responsabilità che i prodotti fabbricati ed immessi in commercio dalla stessa MORETTI S.p.A. e facenti parte della famiglia

LETTINI DA VISITA PROFESSIONALI – LYTUS

UDI-DI di Base: *805287964PREC04KB*

Sono conformi alle disposizioni applicabili del

Regolamento 2017/745 sui DISPOSITIVI MEDICI
del 5 aprile 2017

Ed ai seguenti standard internazionali

EN ISO 14971:2019 – EN ISO 15223-1:2021 – EN 60601-1:2006 – EN 60601-1-2:2015
inclusi successivi emendamenti

A tal scopo la MORETTI S.p.A. garantisce e dichiara sotto la propria esclusiva responsabilità quanto segue:

1. I dispositivi in oggetto soddisfano i requisiti generali di sicurezza e prestazione così come richiesti dall'allegato I del regolamento 2017/745 come prescritto dall'allegato IV del suddetto regolamento.
2. L'elenco completo dei dispositivi in oggetto viene indicato nell'Allegato A della presente dichiarazione.
3. I dispositivi in oggetto NON SONO STRUMENTI DI MISURA.
4. I dispositivi in oggetto NON SONO DESTINATI AD INDAGINI CLINICHE.
5. I dispositivi in oggetto vengono commercializzati in confezione NON STERILE.
6. I dispositivi in oggetto sono da considerarsi come appartenenti alla classe I in conformità a quanto stabilito dall'allegato VIII del suddetto regolamento.
7. La MORETTI S.p.A. mantiene e mette a disposizione delle Autorità Competenti, per almeno 10 anni dalla data di fabbricazione dell'ultimo lotto, la documentazione tecnica di cui agli allegati II e III comprovante la conformità al regolamento 2017/745.
8. I dispositivi in oggetto sono prodotti utilizzando materiali non pericolosi in conformità alla direttiva RoHS - 2011/65/UE

Cavriglia, 09.05.2023

FILIPPO FABBRINI
Amministratore delegato

ALESSANDRO BERTI
PRRC Art.15 MDR 2017/745

Allegati:
Allegato A – Elenco dispositivi medici
Allegato B – Elenco codici UDI-UDI

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C/C Postale 13682521

EU DECLARATION OF CONFORMITY

CE

Regulation EU 2017/745

MORETTI S.p.A.

SRN: *IT-MF-000005980*

declares under its sole responsibility that the product made and traded by Moretti S.p.A.
and belonging to the group of

PROFESSIONAL EXAMINATION COUCHES – LYTUS

Basic UDI-DI*: 805287964PREC04KB*

complies with the

Regulation 2017/745 on MEDICAL DEVICES
of 5 April 2017

and the following international standards

EN ISO 14971:2019 – EN ISO 15223-1:2021 – EN 60601-1:2006 – EN 60601-1-2:2015
including subsequent amendments

For this purpose, Moretti S.p.A. guarantees and declares under its sole responsibility what follows:

1. The devices satisfy the requirements of general safety and performance requested by the Annex I of regulation 2017/745 as laid down by the Annex IV of the above mentioned regulation.
2. The complete list of this range of medical devices is indicated in Annex I
3. The devices *ARE NOT MEASURING INSTRUMENTS*.
4. The devices *ARE NOT MADE FOR CLINICAL TESTS*.
5. The devices are packed in *NON-STERILE BOX*.
6. The devices belong to class I in accordance with the provisions of Annex VIII of the above mentioned regulation
7. Moretti S.p.A. provides to the Competent Authorities the technical documentation set out in Annexes II and III to prove the conformity to the 2017/745 regulation, for at least 10 years from the last lot production.
8. The devices are produced using non-hazardous materials in compliance with the RoHS Directive - 2011/65 / EU

Cavriglia, 09.05.2023

FILIPPO FABBRINI
CEO

ALESSANDRO BERTI
PRRC Art.15 MDR 2017/745

Annexes:
Annex A – Medical devices list
Annex B – UDI-DI codes list

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C/C Postale 13682521

DECLARACIÓN UE DE CONFORMIDAD

CE

Reglamento UE 2017/745

MORETTI S.p.A.

SRN: *IT-MF-000005980*

declara bajo su exclusiva responsabilidad que los productos fabricados y puestos en comercio por la misma MORETTI S.p.A. y que hacen parte de la familia

CAMILLAS DE RECONOCIMIENTO PROFESIONALES – LYTUS

UDI-DI* básico*: *805287964PREC04KB*

cumplen con las disposiciones aplicables del:

Reglamento 2017/745 sobre los
PRODUCTOS SANITARIOS del 5 abril 2017

Y a los siguientes estándares internacionales

EN ISO 14971:2019 – EN ISO 15223-1:2021 – EN 60601-1:2006 – EN 60601-1-2:2015
incluidas las modificaciones posteriores

Por eso, MORETTI S.p.A. garantiza y declara bajo su propia exclusiva responsabilidad lo que sigue:

1. Los productos en cuestión satisfacen los requisitos generales de seguridad y prestación como requerido por el anexo 1 del mismo reglamento 2017/745 como prescrito por el anexo IV del mismo reglamento.
2. La lista completa de los productos en objeto está indicada en el anexo A de esa declaración.
3. Los productos en cuestión NO SON INSTRUMENTOS DE MEDICIÓN.
4. Los productos en cuestión NO ESTÁN DESTINADOS A INVESTIGACIONES CLÍNICAS.
5. Los productos en cuestión se comercializan en presentación NO ESTÉRIL.
6. Los productos en cuestión deben considerarse de clase I en conformidad a lo establecido en el anexo VIII del mismo reglamento.
7. MORETTI S.p.A. mantiene y pone a disposición de las Autoridades Competentes, por 10 años desde la fecha de fabricación del ultimo lote, la documentación técnica especificada en los anexos II y III que comprueba la conformidad con el mismo reglamento 2017/45.
8. Los dispositivos se fabrican con materiales no peligrosos de conformidad con la Directiva RoHS - 2011/65 / EU

Cavriglia, 09.05.2023

FILIPPO FABBRINI
Director General

ALESSANDRO BERTI
PRRC Art.15 MDR 2017/745

Anexos:
Anexo A – Lista productos sanitarios
Anexo B – Lista código UDI-DI

ALLEGATO / ANNEX / ANEXO - A
ELENCO DISPOSITIVI MEDICI / MEDICAL DEVICES LIST / LISTA PRODUCTOS SANITARIOS

Famiglia: **LETTINI DA VISITA PROFESSIONALI – LYTUS**
Group: **PROFESSIONAL EXAMINATION COUCHES – LYTUS**
Familia: **CAMILLAS DE RECONOCIMIENTO PROFESIONALES – LYTUS**

Codice - Code Código	Descrizione	Description	Descripción
MI370X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS	PROFESSIONAL EXAMINATION ELECTRICAL COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS
MI371X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS CON RUOTE	PROFESSIONAL EXAMINATION ELECTRICAL COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS CON RUEDAS
MI380X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS	PROFESSIONAL EXAMINATION ELECTRICAL COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS
MI381X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS CON RUOTE	PROFESSIONAL EXAMINATION ELECTRICAL COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS CON RUEDAS
MI382X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS	PROFESSIONAL EXAMINATION ELECTRICAL COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS
MI383X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS CON RUOTE	PROFESSIONAL EXAMINATION ELECTRICAL COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS CON RUEDAS
MI385X	LETTO DA VISITA PROFESSIONALE IDRAULICO LYTUS	PROFESSIONAL EXAMINATION HYDRAULIC COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL HIDRAULICA LYTUS
MI386X	LETTO DA VISITA PROFESSIONALE IDRAULICO LYTUS CON RUOTE	PROFESSIONAL EXAMINATION HYDRAULIC COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL HIDRAULICA LYTUS CON RUEDAS
MI390X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS LARGE	LARGE PROFESSIONAL EXAMINATION ELECTRICAL COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS LARGE
MI391X	LETTO DA VISITA PROF. ELETTRICO LYTUS LARGE CON RUOTE	LARGE PROFESSIONAL EXAMINATION ELECTRICAL COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS LARGE CON RUEDAS
MI392X	LETTO DA VISITA PROFESSIONALE ELETTRICO LYTUS LARGE	LARGE PROFESSIONAL EXAMINATION ELECTRICAL COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS LARGE
MI393X	LETTO DA VISITA PROF. ELETTRICO LYTUS LARGE CON RUOTE	LARGE PROFESSIONAL EXAMINATION ELECTRICAL COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL ELECTRICA LYTUS LARGE CON RUEDAS
MI395X	LETTO DA VISITA PROFESSIONALE IDRAULICO LYTUS LARGE	LARGE PROFESSIONAL EXAMINATION HYDRAULIC COUCH	CAMILLA DE RECONOCIMIENTO PROFESIONAL HIDRAULICA LYTUS LARGE
MI396X	LETTO DA VISITA PROF. IDRAULICO LYTUS LARGE CON RUOTE	LARGE PROFESSIONAL EXAMINATION HYDRAULIC COUCH WITH CASTORS	CAMILLA DE RECONOCIMIENTO PROFESIONAL HIDRAULICA LYTUS CON RUEDAS

x: Indica il colore del lettino – x: Indicates the color of the couch

Cavriglia, 09.05.2023

ALLEGATO / ANNEX / ANEXO - B
ELENCO CODICI UDI-DI / UDI-DI CODES LIST / LISTA CODIGOS UDI-DI

Famiglia: **LETTINI DA VISITA PROFESSIONALI – LYTUS**
Group: **PROFESSIONAL EXAMINATION COUCHES – LYTUS**
Familia: **CAMILLAS DE RECONOCIMIENTO PROFESIONALES – LYTUS**

MORETTI Codice / Code / Código	UDI-DI Codice / Code / Código
MI370B	08057018718184
MI370BLU	08057018718191
MI370N	08057018718207
MI371B	08057018714858
MI371BLU	08057018714865
MI371N	08057018714872
MI371V	08057018714889
MI380B	08057018718214
MI380BLU	08057018718221
MI380N	08057018718238
MI380V	08057018718245
MI381B	08057018714896

MORETTI Codice / Code / Código	UDI-DI Codice / Code / Código
MI381BLU	0805701871490
MI381N	0805701871491
MI381V	0805701871492
MI385B	0805701871810
MI385BLU	0805701871811
MI385N	0805701871812
MI385V	0805701871813
MI386B	0805701871493
MI386BLU	0805701871494
MI386N	0805701871495
MI386V	0805701871496
MI390B	0805701871825

MORETTI Codice / Code / Código	UDI-DI Codice / Code / Código
MI391B	08057018718290
MI391BLU	08057018718306
MI391N	08057018718313
MI391V	08057018718320
MI395B	08057018718146
MI395BLU	08057018718153
MI395N	08057018718160
MI395V	08057018718177
MI396B	08057018714971
MI396BLU	08057018714988
MI396N	08057018714995
MI396V	08057018715008

MORETTI Codice / Code / Código	UDI-DI Codice / Code / Código
MI382B	08052879644023
MI382BLU	08052879644030
MI382N	08052879644047
MI382V	08052879644054
MI383B	08052879644078
MI383BLU	08052879644085
MI383N	08052879644092
MI383V	08052879644108
MI392B	08052879644122
MI392BLU	08052879644139
MI392N	08052879644146
MI392V	08052879644153

MORETTI Codice / Code / Código	UDI-DI Codice / Code / Código
MI393B	08052879644177
MI393BLU	08052879644184
MI393N	08052879644191
MI393V	08052879644207

Cavriglia, 09.05.2023

BIEFFE ITALIA s.r.l. weiko®
Sede legale: Viale Lincoln, 178 - 81100 Caserta (Italy)
Stabilimento: Consorzio Siné
Zona ASI Aversa Nord 81032 Carinaro (CE)
Tel: +39 081 8654662 Fax: +39 081 8654723
bieffeita@libero.it - www.weiko.com

C.C.I.A.A. 147379
Trib. S. Maria C.V. 16412
P. IVA 02220390617

Bank:
CARIPARMA c/c 000056503302
ABI 06230 CAB 14910 CIN E
IBAN IT75 E 06230 14 910 000056503302
BIC Swift CRP PIT 2P

DECLARATION OF CONFORMITY

CE

Annex IV - 745/2017 MDR

BIEFFE ITALIA s.r.l.

As manufacturer of the products underneath listed, declare under its own responsibility that the products:

BF LED 50.1 - BF LED 50.2 - BF LED 50.3
BF LED 50.4 - BF LED 50.1 F - BF LED 50.2 F
BF LED 50.3 F - BF LED 50.4 F - BF LED 50.1 F I
BF LED 50.2 F I - BF LED 50.3 F I - BF LED 50.4 F I
BF LED 50.1 F T1 - BF LED 50.1 F T2 - BF LED 50.1 F T3

leading to the product family:

SLIM LED VIEWER

BASIC UDI-DI: 805373671LED50.XBP

are in conformity

with the essential requirements of the **745/2017 MDR** as Class I medical devices according to Annex VIII, Chapter III, Rule 1 (one).

Carinaro,13 May 2021

BIEFFE ITALIA S.r.l.
Dr. Flavio Ferrazzano
CEO

Rev.02 – 13 May 2021

Dichiarazione di Conformità

(ai sensi dell'articolo 19 del Regolamento Europeo (UE) 745/2017)

Declaration of Conformity

(according to Article 19 of the European Regulation (EU) 2017/745)

La società / *The company* **MEDI-CARE SOLUTIONS s.r.l.**
Sede legale/*Legal office*: Via Della Zecca N° 1 - 40121 Bologna (BO) Italy
Sede operativa/*Facility*: Via Pietro Nenni 3 - 40026 Imola (BO)- Italy
Tel. ++39 0542 642046 Fax ++39 0542 642355 – Mail: info@euroclinic.it

in qualità di fabbricante dei seguenti dispositivi medici, che vengono immessi in commercio a proprio nome, dichiara sotto la propria esclusiva responsabilità, che il seguente prodotto destinato alla visita e al trattamento in ambito Otorinolaringoiatrico/*as manufacturer of the following MD, which is marketed in its own name, declares under his responsibility, that the following product intended for examination and treatment in the ENT field:*

Denominazione/Modello *Denomination/Model*	**Classificazione, Regola*** *Classification, Rule**	**Numero identificazione (S/N)** *Serial Number*	**UDI-DI** *UDI-DI*
OTOP/V ELEGANCE	**I, Regola 1 e Regola 13** **Class I, Rules 1 and 13**		Non disponibile *Not available*

* secondo l'Allegato VIII Regolamento Europeo (UE) 745/2017
** according to Annex VIII European Regulation (EU) 2017/745*

È conforme ai requisiti essenziali richiesti dall'allegato I del Regolamento Europeo (UE) 745/2017 ed alle seguenti Specifiche Comuni (SC):

- Nessuna applicabile al prodotto

Qualunque modifica apportata ai suddetti dispositivi se non autorizzata da Medi-Care Solutions S.r.l. annulla la validità della presente dichiarazione.

Si dichiara che il fabbricante ha notificato all'autorità competente i suddetti Dispositivi Medici e, in seguito alla immissione in commercio degli stessi, applica specifica procedura di sorveglianza post-vendita dei prodotti come richiesto dal Regolamento Europeo (UE) 745/2017 (articolo 83).

Si dichiara infine che la scrivente terrà a disposizione delle Autorità Sanitarie la documentazione tecnica realizzata ai sensi dell'allegato II e III del Regolamento Europeo (UE) 745/2017 per un periodo di almeno 10 anni a partire dall'ultima data di produzione dei dispositivi in oggetto.

La presente dichiarazione di conformità ha validità 10 anni.

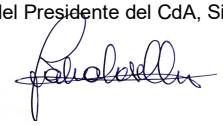
It complies with the essential requirements of Annex I of the European Regulation (EU) 2017/745 and with the following Common Specifications (CS):

- *None applicable to the product*

Every modification applied to the aforementioned devices, without previous Medi-Care Solutions S.r.l authorization, invalidate the present declaration.
The manufacturer declares that has notified to the competent authorities the aforementioned devices and, after placing them in the market, it applies the specific product after-sales surveillance procedure as required by Article 83 European Regulation (EU) 2017/745.
Finally, the manufacturer will keep available the technical documentations at the disposal of the European and National Health Authorities for a period of at least 10 years from the last day of production of the aforementioned devices.
The present declaration of conformity is valid for 10 years.

Direzione Generale
Medi-Care Solutions srl
(Per conto del Presidente del CdA, Sig. Benedetto Uberto Selvatico Estense)

Imola (BO), 07/09/2021



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 Kennummer 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

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
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POTEC

POTEC CO., LTD

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Daejeon, Republic of Korea

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Fax: +82-42-632-3537
Email: sales000@potec.biz

POWER OF ATTORNEY

Hereby we, POTEC Co.,LTD, whose registered office is at 40-4 Techno 2-ro, Yuseong-gu, Daejeon, 34015, Korea hereinafter referred to as "MANUFACTURER", represented by Ko An-soo, acting by president hereby authorizes the company **Tetis International Co SRL** (fiscal code 1003600043595) with registered office at Str. Calea Orheiului, 103/36,Chisinau, MD2020, Moldova, hereinafter referred to as ***"Authorized Manufacturer's Representative":***

- to represent interests of our company in all necessary state bodies and institutions for testing, registration and certification of medical equipment produced by MANUFACTURER;
- to carry out the discussions relating to testing and registration of medical equipment produced by MANUFACTURER;
- to submit all necessary documents to state bodies and institutions;
- to introduce amendments and addendum inserts into documents, to give explanations, to submit additional information;
- to obtain all necessary documents under MANUFACTURER's name;
- to receive the Registration Certificates (electronic of hard copies on paper) under MANUFACTURER's name.

This Power of Attorney is valid for 3 years.

Date: 02 June, 2023

Ko An-Soo
President, Potec Co.,LTD

POTEC CO., LTD.
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Daejeon, 305-509, Korea
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