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. ..... din .....

Solicitantul Vipromed Service SRL, cu sediul str. Valea Trandafirilor 20
(adresa)
Mun. Chisinau, tel./fax: 069567188, e-mail vipromed@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:

CARE 11
CARE 22
CARE 33

Se anexează următoarele acte:
CE Certificate (Ningbo Runyes Medical Instrument Co,. Ltd)
EC Declaration of Conformity
Declaratie pe propria raspundere
Letter of Authorization

Digitally signed by Savca Octavian
Date: 2023.07.03 15:09:03 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	

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: Vipromed Service SRL, cu sediul str. Valea Trandafirilor 20,
(adresa)

Mun. 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:

CARE 11
CARE 22
CARE 33

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

***Octavian SAVCA**, Administrator* *Data* _____

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		UNIT DENTAR	Ningbo Runyes Medical Instrument Co,. Ltd	CARE 11	
		UNIT DENTAR	Ningbo Runyes Medical Instrument Co,. Ltd	CARE 22	
		UNIT DENTAR	Ningbo Runyes Medical Instrument Co,. Ltd	CARE 33	

Letter of Authorization for Authorized Representatives

2023-06-19

Dear Sir/Madam,

Subject: Letter of Authorization for **SRL VIPROMED SERVICE**

We, **Ningbo Runyes Medical Instrument Co.,Ltd**, as the Product Owner, hereby authorize **SRL VIPROMED SERVICE** as our products authorized distributor in the territory of Republic of Moldova.

We authorize **SRL VIPROMED SERVICE** to

- Arrange importation and registration of our products according to legal requirements of regulatory bodies and appropriate government institutions in the territory of Republic of Moldova to ensure maximum success of the marketing of our products.
- Use for marketing purposes the trade name, technical specifications, description and pictures of our products.
- Participate in various tenders.
- Provide the servicing and repairing to our equipment.

This authorization shall apply to the following medical devices:

- Dental units **: CARE 11D; CARE22D; CARE33D; CARE33B; CARE33-M1; CARE33-M2; Maple 62D; Maple 42U.**
- Suction units: **ENROLL-01; ENROLL-05; ENROLL-08.**
- Air compressors: **GIANT – 30; GIANT – 35; GIANT – 40; GIANT – 45; GIANT – 50; GIANT – 55.**

This authorization shall remain until the **1st of June, 2028.**

Yours sincerely,

宁波蓝野医疗器械有限公司
NINGBO RUNYES MEDICAL INSTRUMENT CO.,LTD.

Managing Director of Xu BuGuang
June.19.2023

地址：宁波市江北投资创业园 C 区通惠路 456 号
Add: No. 456 Tonghui Rd,Jiangbei investment pioneering park C, Ningbo,China
Tel: +86-574-27709922 FAX: +86-574-27709923
Website: www.runyes.com Email: runyes@runyes.com

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 088627 0002 Rev. 01

Manufacturer:
Ningbo Runyes Medical Instrument Co., Ltd.
032 Building, No.456, Tonghui Road
Jiangbei Investment & Pioneering Park C
315033 Ningbo
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):
Small Steam Sterilizers,
Diagnostic X-ray Equipment,
Integral Dental Unit Chair

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.: SH18869EXT01

Valid from: 2019-04-23
Valid until: 2024-04-22

Date, 2019-04-18

Stefan Preiß

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

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 088627 0002 Rev. 01

Facility(ies):

Ningbo Runyes Medical Instrument Co., Ltd.
032 Building, No.456, Tonghui Road, Jiangbei Investment & Pioneering Park C, 315033 Ningbo, PEOPLE'S REPUBLIC OF CHINA

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

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

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

EC Declaration of Conformity

In accordance with EC Medical Directive
(93/42/EEC as amended by Directive 2007/47/EC)

Manufacturer	Ningbo Runyes Medical Instrument Co., Ltd. 032 Building, No. 456, Tonghui Road, Jiangbei Investment & Pioneering Park C, 315033 Ningbo, PEOPLE'S REPUBLIC OF CHINA
EC REP	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg , Germany
Product	Integral Dental Unit Chair
Type Reference	Care-11, Care-22, Care-33
Classification	Class IIa, Rule 9
Conformity Assessment Route	Annex II excluding 4
GMDNS Code	47144
Applied Directive	Medical Device Directive (93/42/EEC as amended by Directive 2007/47/EC)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Device, as amended by Directive 2007/47/EC. All Supporting documents are retained under the premises of the manufactures. We are exclusively responsible for the DOC.

Notified Body	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65,D-80339 MÜNCHEN, GERMANY
NB NO.	0123
Certificate No.	No.G1 088627 0002 Rev.01
Validity from	2019-04-23
Validity until	2024-04-22
CEO Signature	**Mr. Buguang Xu**
Place and date	**Ningbo** 2021-01-18

宁波蓝野医疗器械有限公司
NINGBO RUNYES MEDICAL INSTRUMENT CO., LTD.