19013317-6

United States of America

DEPARTMENT OF STATE

To all to whom these presents shall come, Greetings:

I Certify That the document hereunto annexed is under the Seal of the Department of Health and Human Services, United States of America, and that such Seal is entitled to full faith and credit.*

For the contents of the annexed document, the Department assumes no responsibility
This certificate is not valid if it is removed or altered in any way whatsoever

In testimony whereof, I, Michael R. Pompeo, Secretary of State , have hereunto caused the seal of the Department of State to be affixed and my name subscribed by the Assistant Authentication Officer, of the said Department, at the city of Washington, in the District of Columbia, this twenty-eighth day of December, 2018.

Secretary of State

By

Assistant Authentication Officer,
Department of State

Issued pursuant to CHXII, State of Sept. 15, 1789, 1 Stat. 68-69; 22 USC 2657; 22USC 2651a; 5 USC 301; 28 USC 1733 et. seq.; 8 USC 1443(f); RULE 44 Federal Rules of Civil Procedure.

Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ
Embassy of the S.R of Vietnam in the United States of America

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia ..... Việt Nam .....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) ..... Michael R. Pompeo ..... ký
has been signed by

3. với chức danh ..... Bộ trưởng ngoại giao .....
acting in the capacity of

4. và con dấu của ..... Bộ Ngoại giao .....
bears the seal/stamp of

..... Hợp chủng quốc Hoa Kỳ .....

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại ... Washington D.C ..... 6. ngày ... 7 /1 ... 2019 ...
at *the*

7. Cơ quan cấp ... Đại sứ quán Việt Nam tại Hoa Kỳ ....
by

8. Số ..... 69 ..... HPH/2019
No.

Ký tên và đóng dấu
Signature and seal/stamp

Tham tán

Quản Thị Kiều Anh

BẢN DỊCH

Hợp chúng quốc Hoa Kỳ

BỘ NGOẠI GIAO

Hân hạnh kính gửi những người có liên quan:

Tôi xin chứng nhận rằng văn bản đính kèm theo đây được ký và đóng con dấu của Bộ Y tế và Dịch vụ Nhân sinh Hoa Kỳ, và rằng con Dấu này được tin tưởng hoàn toàn.*

Bộ Ngoại giao không chịu trách nhiệm về các nội dung trong văn bản đính kèm.
Giấy chứng nhận này không có giá trị nếu bị tháo rời hay sửa đổi theo bất kỳ cách nào.

Để chứng thực, tôi, Michael R. Pompeo, Bộ trưởng Ngoại giao, đã cho phép đóng dấu của Bộ Ngoại giao và tên của mình được ký bởi Quan chức Hợp pháp hoá của Bộ trên, tại Thành phố Washington, District of Columbia ngày 28/12/2018.

(đã ký và đóng dấu)
Michael R. Pompeo
Bộ trưởng Bộ Ngoại giao
Cán bộ Lãnh sự,
Bộ Ngoại giao

Chứng thực ông Hồ Anh Vũ, Bí thư thứ hai, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, đã ký trước mặt tôi.

Ngày 07 tháng 01 năm 2019
TL. Đại sứ
Tham tán

Quản Thị Kiều Anh

Tôi, Hồ Anh Vũ, Bí thư thứ hai, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, cam đoan đã dịch chính xác văn bản này từ tiếng Anh sang tiếng Việt.

Ngày 07 tháng 01 năm 2019
Người dịch

Hồ Anh Vũ

FOOD & DRUG
ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

...te No. 2745-12-2018

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from December 12, 2018 to December 11, 2020.

Hi u l c L'Jn 11/12/2020

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

...ce No. 2745-12-2018

...cate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

...ame of Manufacturer

Legal Manufacturer/Manufacturer
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
MADISON, WI USA 53718

Name of Distributor
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
MADISON, WI USA 53718

---END OF MANUFACTURER/DISTRIBUTOR LIST---

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

ate No. 2745-12-2018

.cate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

e of Manufacturer

gal Manufacturer/Manufacturer

Datex-Ohmeda, Inc.
3030 Ohmeda Drive
MADISON, WI USA 53718

Ch¸ s´ h¸ u và nhà SX

Name of Product(s)

GAS-MACHINE, ANESTHESIA:
Aestiva MRI
Aisys CS2

Tên s[n phXm

----------END OF PRODUCT LIST----------

ベトナム

MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following medical device marketed by T&S CORPORATION, 433-1 Nanakodai,Noda-shi,Chiba,Japan is manufactured under our supervision as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan, and is certified by Certification Body to be marketed in Japan.

Medical device: Mobile X-ray Diagnostic Apparatus X-BUGGY

Name of Registered Certification Body: Japan Association for the Advancement of Medical Equipment

Certification Number: 228ALBZX00009000

Date of Issue: May 25, 2016

Manufacturing Site and Address: T&S CORPORATION
433-1 Nanakodai, Noda-shi, Chiba, Japan

For legalization by the foreign consul in Japan,
this is to certify that the Seal affixed to this document
is genuine.
Tokyo, APR. 8 2019 T. TANAKA
Official
Ministry of Foreign Affairs
(Consular Service Division)

No. 5828

Tokyo, date MAR. 1 4. 2019

中井清久

Kiyohito Nakai
Director, Medical Device Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN
EMBASSY OF THE S.R. OF VIET NAM IN JAPAN
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: VIỆT NAM
   Country: Viet Nam

   Giấy tờ, tài liệu này
   This public document

2. Do ông (bà): **TOSHIE TANAKA** ký
   Has been signed by
3. Với chức danh: CÔNG CHỨC
   Acting in the capacity of *OFFICIAL*
4. Và con dấu của BỘ NGOẠI GIAO NHẬT BẢN
   Bears the seal/stamp of: *MINISTRY OF FOREIGN AFFAIRS OF JAPAN*

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. Tại: Tô-ki-ô 6. Ngày: 10/04/2019
   At Tokyo *The (dd/mm/yyyy)*
7. Cơ quan cấp: ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN
   By EMBASSY OF THE S.R. OF VIET NAM IN JAPAN
8. Số: **10/04/19-01P/HPHLS**
   N°

TL. Đại sứ/For the Ambassador
Bí thư thứ nhất/First Secretary

NGUYỄN AN TIẾN

I, Silvia Leso, an officer of the Department of Foreign Affairs and Trade, Melbourne, having been duly authorised by the Secretary of the Department of Foreign Affairs and Trade, **DO HEREBY CERTIFY** that the signature/seal/stamp Malinda Hou-Ju Kuo, Notary Public, appearing on the document/s attached hereto is the true signature/seal/stamp of Malinda Hou-Ju Kuo. In so certifying, neither I nor the Department of Foreign Affairs and Trade, Melbourne endorse, verify or make any statement as to the accuracy, truth, legality or otherwise of the contents of the document or the purposes for which the document may be used. Neither I nor the Department of Foreign Affairs and Trade, Melbourne accept liability for any loss, damage or injury arising out of the use of, or reliance on, the document or its contents. I provide no undertaking that I have read the contents of the document.

GIVEN under my Hand and the seal of the Department of Foreign Affairs and Trade, Melbourne the 19th day of February, 2020.

Silvia Leso
Authentication Officer
For the Secretary
Department of Foreign Affairs and Trade, Melbourne

DEPT OF FOREIGN AFFAIRS AND TRADE * MELBOURNE *

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia ..... Việt Nam .....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) ..... Silvia Leso ..... ký
has been signed by

3. với chức danh ..... Viên chức .....
acting in the capacity of

4. và con dấu của ..... Bộ Ngoại giao và Thương mại Ô-xtơ-rây-li-a .....
bears the seal/stamp of

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại ..... Can-be-ra ..... 6. ngày 24 / 02 / 2020
at *the*

7. Cơ quan cấp ..... Đại sứ quán nước CHXHCN Việt Nam tại Ô-xtơ-rây-li-a
by

8. Số 92 - 2020 / CNLS/HPHLS
No

Ký tên và đóng dấu
Signature and seal/stamp
TL. Đại sứ/For the Ambassador
Bí thư thứ Hai/Second Secretary

Vương Thị Hoàng Yến

ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI ÚC

Australian Government

Department of Health

Therapeutic Goods Administration

CERTIFICATE OF FREE SALE

Certificate Number: 19/391

Products:

ARTG Entry	Device Description	GMDN Code	Class
243013	Lasers, Ophthalmic, Nd:YAG	16947	IIb
118348	Ophthalmic solid-state laser system, photocoagulation	62197	IIb
192542	Ultrasound system, imaging, ophthalmic	11389	IIa
224484	Surgical frequency-doubled Nd:YAG laser system	36150	IIb

Sponsor:

Ellex Medical Pty Ltd
3-4 Second Avenue
Mawson Lakes SA 5095
Australia

Manufacturer:

Ellex Medical Pty Ltd
3-4 Second Avenue
Mawson Lakes SA 5095
Australia

I certify that this is a true copy of the original document

Malinda Hou-Ju Kuo
Notary Public, Adelaide, South Australia, Australia
My appointment is not limited by time

The kinds of medical devices specified above and in the attached schedule are included in the Australian Register of Therapeutic Goods (ARTG) and as such are available for supply and free sale in, or export from, Australia.

The attached schedule is part of this certificate and contains product details supplied by the sponsor. There is one (1) schedule comprising one (1) page attached to this certificate.

The sponsor has declared that the products set out in the attached schedule(s) relate to the kinds of medical devices currently included in the ARTG as specified.

Veronica Scola
Delegate of the Secretary
Export Section
9 December 2019

Australian Government
Department of Health

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email : info@tga.gov.au

Australian Government

Department of Health

Therapeutic Goods Administration

19/391

Schedule 1 to Certificate Number 19/391

ARTG	Trade / Product Name	GMDN
118348	Integre Pro LP5532 Integre Pro LP1RG Integre Pro LP561 Integre Pro L2RY	62197
118348	Integre Pro Scan LP6G Integre Pro Scan LP6RG Integre Pro Scan LP6RY Integre Pro Scan LP6Y	62197
243013	Tango LT5106-T Tango Reflex LT5106-T Ultra Q Reflex LQP3106-U Ultra Q LQP3106-U Solo LT5106-S	16947
192542	EyeCubed I3 System ABDU EyeOne Eye Prime	11389
224484	2RT LR1532	36150

MALINDA HOU-JU KUO
Notary Public
SOUTH AUSTRALIA

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email : info@tga.gov.au

THE DEPARTMENT OF FOREIGN AFFAIRS, TRADE AND DEVELOPMENT CANADA HAS DULY AUTHENTICATED THE SIGNATURE, AFFIXED ON THE UNDERLYING DOCUMENT, OF:

LE MINISTÈRE DES AFFAIRES ÉTRANGÈRES, COMMERCE ET DÉVELOPPEMENT CANADA A DÛMENT AUTHENTIFIÉ LA SIGNATURE, APPOSÉE SUR LE DOCUMENT SOUS-JACENT, DE:

FOR THE DEPUTY MINISTER OF FOREIGN AFFAIRS / POUR LE SOUS-MINISTRE DES AFFAIRES ÉTRANGÈRES:

/MICHAEL GABRIELS

DATE: MAR 13 2019

OTTAWA, CANADA

THE DEPARTMENT DOES NOT VALIDATE THE CONTENT OF THE UNDERLYING DOCUMENT. LE MINISTÈRE NE VALIDE PAS LE CONTENU DU DOCUMENT SOUS-JACENT

Department of Foreign Affairs, Trade and Development Canada

Ministère des Affaires étrangères, Commerce et Développement Canada

Medicines & Healthcare products Regulatory Agency

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
mhra.gov.uk

SAE 188/V14228/1

13/02/2019 09:50:59

Medicines and Healthcare Products Regulatory Agency

On behalf of the Department of Health

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS TO

VIETNAM

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by; **Canafusion Technologies Inc.,** #302-2999 Underhill Avenue Burnaby, BC V5A 3C2 Canada, have been affixed with the CE mark under the Medical Devices Directive 93/42/EEC as transposed into UK legislation (UK Medical Devices Regulations 2002 SI No. 618, as amended), and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

See attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

Gbemisola Sunmon

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA

Certified to be a True Copy of the Original Document

APR 24 2019

Jennifer Kwok
Notary Public
#2110 - 1163 Pinetree Way
Coquitlam, BC, V3B 8A9
P.604-332-2288 F.604-670-6688

JENNIFER M.E. SEE KWOK NOTARY PUBLIC BRITISH COLUMBIA

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI CANADA
EMBASSY OF THE S.R. OF VIETNAM IN CANADA

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: *Viet Nam*
   Country

   Giấy tờ, tài liệu này
   This public document
2. do Ông (Bà): Michael Gabrario ký
   has been signed by
3. với chức danh: Thừa ủy quyền Thứ trưởng Ngoại giao
   acting in the capacity of
4. và con dấu của: Bộ Ngoại giao, Thương mại và Phát triển Ca-na-đa
   bears the seal/stamp of

Được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. tại Ót-ta-oa 6. Ngày 03/6/2019
   at *the*
7. Cơ quan cấp: Đại sứ quán Việt Nam tại Ca-na-đa
   by
8. Số/: 35/16/2019/CNLS/HPHLS
   N°

Ký tên và đóng dấu
Signature and Seal/Stamp
Tham tán

Vũ Hoàng Yến

ĐẠI SỨ QUÁN C.H.X.H.C.N VIỆT NAM TẠI C-NA-ĐA

Schedule of Devices requested for	ord-20190212-011021-wrdf
Ordered on	12/02/2019
Directive/Class	93/42/EEC
Mfr Name	Canafusion Technologies Inc.

Legal manufacturer:					
Canafusion Technologies Inc.					
#302-2999 Underhill Avenue Burnaby BC V5A 3C2 Canada.					
Product list:					
#	**Product**	**Brand**	**Model**	**Class**	**UMDNS Code**
1	Infusion Pumps	Canafusion	CA-2000	IIb	13215
2	Syringe Pumps	Canafusion	CA-500 1 CA-700 2 CA-3000 3	IIb	13217
3	Enteral Feeding Pumps	Canafusion	CA-1000	IIa	13209

End of schedule. No additional products past this point.

Certified to be a True Copy
of the Original Document

APR 24 2019

Jennifer Kwok
Notary Public
#2110 - 1163 Pinetree Way
Coquitlam, BC, V3B 8A9
P.604-332-2288 F.604-670-6688

JENNIFER MEI SEE KWOK NOTARY PUBLIC BRITISH COLUMBIA

Gewerbeaufsicht
in Niedersachsen

Staatliches Gewerbeaufsichtsamt Hannover
Behörde für Arbeits-, Umwelt- und Verbraucherschutz

Bescheinigung der Verkehrsfähigkeit von Medizinprodukten

Bestätigung der Verkehrsfähigkeit von Medizinprodukten gemäß § 34 (1) des Medizinproduktegesetzes (MPG) in der gegenwärtig gültigen Fassung.

Zur Vorlage bei den zuständigen Behörden oder Einrichtungen von **Vietnam**

Es wird bescheinigt, dass die nachfolgend genannten Medizinprodukte

- in Deutschland
- in den Mitgliedstaaten der Europäischen Union und
- in den anderen Vertragsstaaten des Abkommens über den Europäischen Wirtschaftsraum uneingeschränkt verkehrsfähig sind.

Produkte:
siehe Anlage A

Hersteller:
Profound Medical Inc.
2400 Skymark Avenue, Unit 6
L4W 5K5 Mississauga, ON
CANADA

Bevollmächtigter
Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Deutschland

Es wird auch bescheinigt, dass mit dem Anbringen der CE-Kennzeichnung der Hersteller das vorgeschriebene Konformitätsbewertungsverfahren befolgt, sicherstellt und erklärt, dass die Medizinprodukte die Grundlegenden Anforderungen der Richtlinie des Rates 93/42/EWG vom 14. Juni 1993 in der gegenwärtig gültigen Fassung erfüllen.

Certificate of Marketability of Medical Devices

Confirmation of marketability of medical devices according to § 34 (1) of the Medical Devices Law (MPG) in the present valid version.

For presentation to the competent authorities or bodies of **Vietnam**

It is certified that the following medical devices can be marketed without restriction within

- Germany
- the member states of the European Union and
- the other states having a contractual agreement with the European Economic Area.

Products:
see Annex A

Manufacturer:
Profound Medical Inc.
2400 Skymark Avenue, Unit 6
L4W 5K5 Mississauga, ON
CANADA

Authorized Representative:
Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

It is also certified that with the affixing of the CE-mark, the manufacturer follows the prescribed conformity assessment procedure and ensures and declares that the medical devices meet the essential requirements of the Council Directives 93/42/EEC of 14. June 1993 in the present valid version.

STAATLICHES GEWERBEAUFSICHTSAMT HANNOVER
Am Listholze 74
30177 Hannover

Hannover, 12.07.2018

H906062109-7-223

Im Auftrage

Fox

STAATL. GEWERBEAUFSICHTSAMT 5 HANNOVER

Sprechzeiten
Mo-Do: 8:00 - 16:00 Uhr
Freitag: 8:00 - 14:30 Uhr
oder nach Vereinbarung

Telefon 0511 9096-0
Fax 0511 9096-199
E-Mail poststelle@gaa-h.niedersachsen.de
Internet www.gewerbeaufsicht.niedersachsen.de

Bankverbindung
Norddeutsche Landesbank
IBAN: DE62 2505 0000 0106 0252 16
SWIFT-BIC: NOLADE2H

Anlage A / Annex A

Product	Registration	GMDN	Risk class
Sonalleve MR-HIFU Sonalleve MR-HIFU V2 ACHIEVA 1.5T 451000080766 Sonalleve MR-HIFU V2 ACHIEVA 3T 451000080776 Sonalleve MR-HIFU V2 INGENIA 1.5T 451000080786 Sonalleve MR-HIFU V2 INGENIA 3T 451000080796 **Upgrade Kits:** Upgrade Kit for SONALLEVE MR-HIFU V1 ACHIEVA 1.5T 989603082552 Upgrade Kit for SONALLEVE MR-HIFU V1 ACHIEVA 3T 989603082562 Upgrade Kit for SONALLEVE MR-HIFU V2 INGENIA 1.5T 989603082472 Upgrade Kit for SONALLEVE MR-HIFU V2 INGENIA 3T 989603082482 Upgrade Kit for SONALLEVE MR-HIFU V2 ACHIEVA 1.5T 989603082452 Upgrade Kit for SONALLEVE MR-HIFU V2 ACHIEVA 3T 989603082461	DE/CA09/0170/P37/002	40781	IIb

Die Echtheit ~~vorstehender~~/umseitiger Unterschrift
der/~~des~~ Frau Fox
~~in~~/bei dem Gewerbeaufsichtsamt Hannover
und die Echtheit des beigefügten
Dienstsiegels/~~Dienststempels~~ werden hiermit beglaubigt

Gleichzeitig wird bescheinigt, daß die/~~der~~ Vorgenannte
zur Ausstellung dieser Urkunde/zur Vornahme der
Amtshandlung berechtigt ist/war.

Hannover, den 18.07.2018

Polizeidirektion Hannover

Im Auftrage

Przyklenk

Przyklenk

Beschäftigte

POLIZEIDIREKTION HANNOVER 62

Dieses Dokument wurde von einer
in Deutschland / Europäischen Union
zuständigen Stelle / Institution /
Behörde ausgestellt.

Gebührenmarke EUR

Hannover, den 18. Juli 2018

IHK Hannover

Industrie- u. Handelskammer
Hannover
im Auftrage

~~(Bemme)~~

INDUSTRIE- UND HANDELSKAMMER HANNOVER 51

CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
KONSULARISCHE BEGLAUBIGUNG/LEGALISIERUNG

1.Quốcgia/Staat:**Việt Nam/Vietnam**

Giấy tờ, tài liệu này/Dieses Dokument

2.Với chữ ký của/U. von Herrn (Frau):

3.Với chức danh/Funktion:

4. Và con dấu của/Dienstsiegel von: **Phòng Thương mại và Công nghiệp Hannover**

được chứng nhận/hợp pháp hóa lãnh sự/
wird hiermit konsularisch beglaubigt/legalisiert

5.Tại/in: **Berlin** 6. Ngày/Datum: **07/08/2018**

7.Cơ quan cấp/Ausgestellt von: **Đại sứ quán nước CHXHCN Việt Nam tại CHLB Đức Botschaft der SR Vietnam in der BR Deutschland**

8. Số/Nr.: **08b-LS-HPH/2018**

T.L. Đại sứ/i.A. des Botschafters
Bí thư thứ Ba/III. Sekretär

Bùi Đức Minh

364 521

swissmedic

Swiss Agency for Therapeutic Products swissmedic

Free Sales Certificate

FOR THE HEALTH AUTHORITIES OF VIETNAM

Certificate n° 00006266 Valid until 25.06.2023

The SWISS AGENCY FOR THERAPEUTIC PRODUCTS, SWISSMEDIC, authorizes and supervises therapeutic products (medicinal products and medical devices). In Switzerland medical devices are regulated under the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) which incorporates the European legislation. On the basis of the documents submitted, Swissmedic certifies that the medical device(s) specified hereunder can be placed on the market in Switzerland and its treaty countries without restrictions.

- see attached list of 1 page(s)

Companies involved in the manufacturing or the supplying of these medical devices:

- Ordering company:	Baxter Healthcare SA, Postfach, 8010 Zurich, CH (Role: Legal manufacturer)
- Production site:	Baxter S.A., 80 Boulevard Renè Branquart, 7860 Lessines, BE

Bern, 25.06.2020
Swiss Agency for Therapeutic Products
Medical Devices Division

Claudia Gugler

012142
No.
Seen for legalization of
the above signature
Berne, -2 JUL 2020
SWISS FEDERAL CHANCELLERY
A. Manoiero
Alessandra Manoiero

SWISS FEDERAL CHANCELLERY
Tax CHF 20.-

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

ĐẠI SỨ QUÁN VIỆT NAM TẠI THUỴ SỸ
EMBASSY OF VIET NAM IN SWITZERLAND

CHỨNG NHẬN / HỢP PHÁP HOÁ LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: Việt Nam
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà): Alessandra Manoiero ký
has been signed by

3. với chức danh:
acting in the capacity of

4. và con dấu của: Văn phòng Liên bang
bears the seal/stamp of

được chứng nhận / hợp pháp hoá lãnh sự
Certified

5. tại: BERN
at

6. ngày 9 / 7/ 2020
the

7. Cơ quan cấp: Embassy of Viet Nam in Switzerland
by

8. Số: 754 /CNLS/HPHLS
N°

Ký tên và đóng dấu
Signature and seal/stamp
TL. ĐẠI SỨ
THAM TÁN

Nguyễn Thành Huy

Baxter

Baxter Healthcare SA
P.O. Box
8010 Zurich
Switzerland

Medical Products

PRODUCT CODE LIST

Code	Description	Medical Device Class	GMDN Code
1503745	Hemopatch 2.7 x 2.7 cm, 5-PK	III	47201 (Collagen haemostatic agent)
1503746	Hemopatch 4.5 x 4.5 cm, 3-PK	III	47201 (Collagen haemostatic agent)
1503747	Hemopatch 4.5 x 9 cm, 3-PK	III	47201 (Collagen haemostatic agent)
1506253	Hemopatch 4.5 x 9 cm, 3-PK	III	47201 (Collagen haemostatic agent)
1506256	Hemopatch 4.5 x 4.5 cm, 3-PK	III	47201 (Collagen haemostatic agent)
1506257	Hemopatch 2.7 X 2.7 cm, 5-PK	III	47201 (Collagen haemostatic agent)

Print No. - 200.222779 - Page 2/2

247929

Free Sales Certificate

The Danish Medicines Agency hereby certifies that the medical devices specified in the attached list are manufactured by:

Dameca A/S
Islevdalvej 211
2610 Rødovre
Denmark

Medical devices which are CE marked in conformity with Directive 93/42/EEC meet the essential requirements for safety and performance. They may therefore be manufactured and marketed in Denmark and exported without any approval from the Danish Medicines Agency.

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Ugur Erman

Ugur Erman

Valid from: 19 January 2019
Valid Until: 19 January 2021

PRODUCT LIST

Anaesthesia Workstations:

Siesta iTS
Siesta i Whispa
Dameca MRI508

Dameca AX500

Intellisave AX700

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

APOSTILLE (Convention de La Haye du 5 octobre 1961)			
1. Country: Land:	**Denmark** Danmark		
This public document Dette offentlige dokument			
2. has been signed by er underskrevet af	**Ugur Erman**		
3. acting in the capacity of i egenskab af	**Scientific Officer** Videnskabelig Funktionær		
4. bears the seal/stamp of er forsynet med segl/stempel af	**Danish Medicines Agency** Lægemiddelstyrelsen		
Certified Attesteret			
5. at i	**Copenhagen** København	**6. the** den	**04 Jul 2019** 04 jul 2019
7. by af	**Ministry of Foreign Affairs of Denmark** Udenrigsministeriet		
8. No nr.	**6EBFE50F**		
9. Seal/stamp: Segl/stempel:	MINISTRY OF FOREIGN AFFAIRS	**10. Signature:** Underskrift:	Pia Ejdal Frandsen

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued.

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MINISTRY OF FOREIGN AFFAIRS

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI ĐAN MẠCH
EMBASSY OF THE S.R OF VIET NAM IN DENMARK

CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: **VIỆT NAM**
Country: Viet Nam
Giấy tờ, tài liệu này
This public document
2. do Ông (Bà) **PIA EJDAL FRANDSEN** ký
has been signed by PIA EJDAL FRANDSEN
3. với chức danh **Cán bộ hành chính**
acting in the capacity of Administrative Officer
4. và con dấu của **BỘ NGOẠI GIAO ĐAN MẠCH**
bears the seal/stamp of the Ministry of Foreign Affairs of Denmark
được chứng nhận/hợp pháp hóa lãnh sự
Certified
5. tại **COPENHAGEN** 6. ngày **08/07/2019**
at Copenhagen 08 July 2019
7. Cơ quan cấp: ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI ĐAN MẠCH
by Embassy of the S.R. of Viet Nam in Denmark
8. Số: 34.07/HPHLS/19 *No: 34.07/HPHLS/19*

Tham tán Công sứ / Minister Counsellor

Phạm Thị Thanh Bình

PS/DP/CGM 484/2019-CERT.

Dª. Carmen Ruiz-Villar Fernández-Bravo, Jefe del Departamento de Productos Sanitarios de la Agencia Española de Medicamentos y Productos Sanitarios,

CERTIFICA:

Que la empresa **OSATU, S.COOP**, con sede en **EDIFICIO ZEARREKOBUELTA, SUBIDA DE AREITIO, 5 - 48260 ERMUA (VIZCAYA) ESPAÑA**, cuenta con licencia previa de funcionamiento como fabricante de productos sanitarios, en aplicación de la legislación española, correspondiéndole el N º 5064-PS

En base a las declaraciones y/o certificados aportados, los productos fabricados que figuran en el Anexo I adjunto de 1 página, disponen de marcado CE de acuerdo a lo previsto en el Real Decreto 1591/2009 de 16 de octubre, transposición a la legislación nacional de la Directiva 93/42/CEE del Consejo de 14 de junio de 1993 relativa a los productos sanitarios, lo que permite su comercialización en España y en el resto de países de la Unión Europea no existiendo trabas para su exportación.

Asimismo, ha presentado la declaración adicional que figura en el Anexo II al final del documento.

Este certificado se expide en base a la información contenida en las bases de datos de la AEMPS y a la documentación presentada por la empresa en el momento de la emisión y no supone una autorización sanitaria de comercialización de los productos por parte de esta Agencia.

Y para que conste y surta los efectos oportunos **ANTE QUIEN CORRESPONDA,** lo firmo en Madrid, a quince de julio de dos mil diecinueve.

agencia española de medicamentos y productos sanitarios
Celia Barquilla Díaz
Subdirectora de Productos Sanitarios

CORREO ELECTRONICO
sgps@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91 822 52 89

U 05445537 Traductora-Intérprete Jurada de Inglés

ANEXO I AL CERTIFICADO N º 484/2019 EMITIDO A FAVOR DE LA EMPRESA OSATU, S.COOP, DE FECHA 15 DE JULIO DE 2019

- **Desfibrilador Externo Automático / Automatic External Defibrillator "REANIBEX 200"**
- **Monitor-Desfibrilador Bifásico / Biphasic Defibrillator-Monitor "REANIBEX 700"**
- **Monitor-Desfibrilador Bifásico / Biphasic Defibrillator-Monitor "ELIFE 700"**
- **Monitor-Desfibrilador Bifásico / Biphasic Defibrillator-Monitor "RELIFE 700"**
- **Monitor-Desfibrilador Bifásico / Biphasic Defibrillator-Monitor "REANIBEX 800"**
- **Desfibrilador Externo Automatizado / Automatic External Defibrillator "REANIBEX-300"**
- **Monitor-Desfibrilador Bifásico / Biphasic Defibrillator-Monitor "REANIBEX 500"**

CORREO ELECTRONICO
sgps@aemps.es
Celia Barquilla Díaz
Traductora-Intérprete Jurada
C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91 822 52 89

ANEXO II AL CERTIFICADO Nº 484/2019 EMITIDO A FAVOR DE LA EMPRESA OSATU, S.COOP, DE FECHA 15 DE JULIO DE 2019

La empresa **OSATU, S.COOP**, declara:

- Que por otra parte, y aún siendo una norma voluntaria, ha obtenido la certificación frente a la norma EN-ISO 13485 "Productos sanitarios. Sistemas de Gestión de la calidad. Requisitos para fines reglamentarios" que asegura el cumplimiento de los requisitos correspondientes de los anexos de la citada directiva y que son equivalentes a las buenas prácticas de fabricación exigidas por otros países.

I, Celia Barquilla Díaz, sworn translator authorized by the Spanish Ministry of Foreign Affairs to translate official documents from and into the English language, do hereby certify that the following is a true and faithful English rendering of a copy of a document submitted to me in Spanish.

Celia Barquilla Díaz

Traductora-Intérprete Jurada de Inglés

N.º 8007

[Coat of arms of Spain]
MINISTRY OF HEALTH, CONSUMER AFFAIRS AND SOCIAL WELFARE

The Spanish Agency for Medicine and Medical Devices

MEDICAL DEVICES DEPARTMENT

PS/DP/CGM 484/2019-CERT.

I, Ms. Carmen Ruiz-Villar Fernández-Bravo, Head of Medical Devices Department of the Spanish Agency for Medicine and Medical Devices,

CERTIFY:

That the company **OSATU, S.COOP**, with registered office at **EDIFICIO ZEARREKOBUELTA, SUBIDA DE AREITIO, 5 - 48260 ERMUA (VIZCAYA) ESPAÑA [SPAIN]**, holds a prior licence under no. 5064-PS to operate as a manufacturer of medical devices, in application of Spanish legislation.

Based on the statements and/or certificates provided, the manufactured devices that appear in the attached Annex I of one page, have the CE marking pursuant to Royal Decree 1591/2009 of 16 October, transposition into national law of the Directive 93/42/EEC of the Council of 14 June 1993 relating to medical devices, which allows the marketing in Spain and in the other countries of the European Union, there being no legal impediments to exportation.

Furthermore, the aforementioned company has provided an additional statement that appears at the end of Annex II.

This certificate is issued based on the data contained in the AEMPS (The Spanish Agency for Medicine and Medical Devices) databases and on the documents provided by this company at the time of this issuance and it does not presume any health authorisation by this Agency to commercialise products.

In witness whereof TO WHOM IT MAY CONCERN, I sign this document at Madrid, this fifteenth day of July two thousand and nineteen.

[Stamp: Spanish Agency for Medicine and Medical Devices. Medical Devices Department]

[Illegible signature]

E-MAIL
sgps@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91822 52 89

Celia Barquilla Díaz
Traductora-Intérprete Jurada de Inglés
N.º [illegible]

U05443535

ANNEX I TO CERTIFICATE NO. 484/2019 ISSUED IN FAVOUR OF THE COMPANY OSATU, S.COOP, ON 15 JULY 2019

- **Automatic External Defibrillator "REANIBEX-200"**
- **Biphasic Defibrillator-Monitor "REANIBEX 700"**
- **Biphasic Defibrillator-Monitor "ELIFE 700"**
- **Biphasic Defibrillator-Monitor "RELIFE 700"**
- **Biphasic Defibrillator-Monitor "REANIBEX 800"**
- **Automatic External Defibrillator "REANIBEX 300"**
- **Biphasic Defibrillator-Monitor "REANIBEX 500"**

[Stamp: Spanish Agency for Medicine and Medical Devices. Medical Devices Department]

E-MAIL
sgps@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91822 52 89

Celia Barquilla Díaz
Traductora-Intérprete Jurada de Inglés
Nº 9007

[Coat of arms of Spain]
MINISTRY OF HEALTH, CONSUMER AFFAIRS AND SOCIAL WELFARE

The Spanish Agency for Medicine and Medical Devices

MEDICAL DEVICES DEPARTMENT

ANNEX II TO CERTIFICATE NO. 484/2019 ISSUED IN FAVOUR OF THE COMPANY OSATU, S.COOP, ON 15 JULY 2019

The Company Osatu, S.Coop declares:

- Furthermore, and still being a voluntary standard, the aforementioned company has obtained the certification for the EN-ISO 13485 Standard "Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes", which ensures compliance with the corresponding requirements of the annexes of the aforementioned Directive and which are equivalent to the good manufacturing practices required by other countries.

[Stamp: Spanish Agency for Medicine and Medical Devices. Medical Devices Department]

E-MAIL
sgps@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91822 52 89

Celia Barquilla Díaz
Traductora-Intérprete Jurada de Inglés
[illegible]2007

UQ5443534

This translation appears on five pages, numbered from 1 to 5, each of which carries my signature and seal.

Witness my hand, this 12th day of September 2019.

Celia Barquilla Díaz

Traductora-Intérprete Jurada de Inglés

N.º: 8007

Signed: Celia Barquilla Díaz.

Yo, **NESTOR JOSE ALMARZA DE LA PEÑA,** Notario de Durango, del Ilustre Colegio del País Vasco, **DOY FE.**----------

De que la fotocopia que antecede, extendida en cuatro folios de los Colegios Notariales de España, serie UQ, números 5443537 y los tres correlativos anteriores, coinciden fielmente con el original que reproduce y he tenido a la vista.----------

En Durango, a veintinueve de octubre de dos mil diecinueve.----------

Libro Indicador Nº **1**----------

Asiento Nº 238.----------

FE PÚBLICA NOTARIAL
CONSEJO GENERAL DEL NOTARIADO ESPAÑOL
NOTARIADO EUROPA
NIHIL PRIUS FIDE
0234311571

SELLO DE LEGITIMACIONES Y LEGALIZACIONES
NIHIL PRIUS FIDE
A262103813

LEGALIZACIÓN: Visto en esta Dirección General de los Registros y del Notariado para legalizar la firma de D. Álvaro Rodríguez Santos. Miembro de la Junta Directiva del Colegio Notarial del País Vasco.

Madrid, 07 de noviembre de 2019

P.D. de la Directora General

Funcionaria Autorizada de Legalizaciones

Fdo. Mª. Josefa Crespo Chivo

MINISTERIO DE JUSTICIA
SUBSECRETARÍA

MINISTERIO DE ASUNTOS EXTERIORES Y DE COOPERACION
LEGALIZACIONES
Visto Bueno para legalizar la firma que antecede por ser, al parecer, auténtica, sin prejuzgar la veracidad del contenido del documento ni ulterior destino que pueda dársele.

Madrid, 07 NOV 2019

P. EL SUBSECRETARIO

Mª Teresa Gómez García-Oliva
Jefe de Negociado

UQ5443533

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI TÂY BAN NHA
EMBASSY OF THE S.R. OF VIETNAM IN SPAIN

CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: **VIỆT NAM**
Country:

Giấy tờ, tài liệu này
This public document

2. Do Ông (Bà): **Ma. Teresa Gomez Garcia – Oliva** ký
Has been signed by

3. Với chức danh: **Trưởng phòng**
Acting in capacity of

4. Và con dấu của **Bộ Ngoại giao và Hợp tác Tây Ban Nha**
Bearing the seal/ stamp of

Được chứng nhận/ hợp pháp hóa lãnh sự
Certified

5. Tại **Ma-đờ-rít** Ngày 07 / 11 /2019
At *the (dd/mm/yyyy)*

6. Cơ quan cấp: **Đại sứ quán Việt Nam tại Tây Ban Nha**
by

7. Số 6359/**CNLS/HPHLS**
No

Ký tên và đóng dấu
Signature and seal/ stamp
Bí thư thứ hai/ Second Secretary

Nguyễn Tô Lan Phương

El presente folio es el agregado al documento en el que figura la firma de DON NESTOR JOSE ALMARZA DE LA PEÑA, Notario del Ilustre Colegio Notarial del País Vasco, con residencia en Durango, extendido en cinco folios de los Colegios Notariales de España, serie UQ, número 5443537 y los cuatro, bajo testimonio, autorizado el día veintinueve de octubre de dos mil diecinueve, número 238 de su libro indicador.----------

Álvaro Rodríguez Santos, Subdelegado del Colegio Notarial del País Vasco, en calidad de Decano accidental, **LEGALIZO,** el signo, firma y rúbrica que figura en el documento reseñado del Notario de Durango, DON NESTOR JOSE ALMARZA DE LA PEÑA.----------

DURANGO, a veintinueve de octubre de dos mil diecinueve.----------

FE PÚBLICA NOTARIAL
CONSEJO GENERAL DEL NOTARIADO ESPAÑOL
NOTARIADO EUROPA
NIHIL PRIUS FIDE
0234403018

SELLO DE LEGITIMACIONES Y LEGALIZACIONES
0,15
NIHIL PRIUS FIDE
A092102642

LEGALIZACIÓN: Visto en esta Dirección General de los Registros y del Notariado para legalizar la firma de D. Álvaro Rodríguez Santos. Miembro de la Junta Directiva del Colegio Notarial del Pais Vasco.

Madrid, 07 de noviembre de 2019

P.D. de la Directora General

Funcionaria Autorizada de Legalizaciones

Fdo. Mª. Josefa Crespo Chivo

MINISTERIO DE JUSTICIA
SUBSECRETARÍA

MINISTERIO DE ASUNTOS EXTERIORES Y DE COOPERACION
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Madrid, 07 NOV 2019

P. EL SUBSECRETARIO

Mª Teresa Gómez García-Oliva
Jefe de Negociado

UQ5439471

OGYÉI
National Institute of
Pharmacy and Nutrition

Department of Medical Devices

H-1051 Budapest, Zrínyi u. 3.
1372 P.O. Box:450.
Tel: +36 1 88 69 300, Fax: +36 1 88 69 460
E-mail: ogyei@ogyei.gov.hu, Web: www.ogyei.gov.hu

Case No.: **OGYÉI/16655-3/2020**
Subject: Certificate for third countries
Consultant: Henrietta Kopornoky

FREE SALES CERTIFICATE

On request of the **Labtech Kft.** (4031 Debrecen, Vág u. 4. Hungary) the National Institute of Pharmacy and Nutrition hereby certifies, that on the basis of information provided, the medical device(s) named below and detailed in the attachment (if applicable), which is/are manufactured by the above economic operator, has/have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices and/or the Council Directive 93/42/EEC concerning medical devices (as amended) which was transposed into Hungarian national law [decree No. 8/2003. (III. 13) of the Ministry of Health, Social and Family Affairs on in vitro diagnostic medical devices and /or decree No. 4/2009 (III. 17) of the Ministry of Health on medical devices, as amended] may be freely sold in all member states of the European Economic Area (EEA) including Hungary.

EC type Holter systems
with Cardiospy software
including EC-2H, EC-3H, EC-12H, EC-ABP, EC-3H/ABP models

EC type resting and stress test ECG systems
with Cardiospy software
including EC-12R, EC-12RM, EC-12S, EC-12R/S, EC-3RT, EC-12RT, EC-12LT models

This certificate has been issued to Hungarian exporters for use in third countries to support the application for permission of placing the above mentioned devices on the market.
A Free Sales Certificate should not be taken as a Government endorsement of any product that is referred to on the certificate or its attachment.

Budapest, 19 March 2020

dr. Kornél Szerdi
Head of Department

dr. Hodosi, Gábor
Civil Law Notary
holder of a language license in English and German
appointed to Notarial Seat No. 1 of Hajdúböszörmény
official electronic contact information in short: MOKKIT
Seat Code: K32018 , KRID: 342479118
H-4220 Hajdúböszörmény, Hungary, Bocskai tér 2.
Tel: + 36 52 561-042 , Tel: + 36 52 561-043
Email: iroda.hodosi@kozjegyzo.hu

English language license No: 2/2017.
File No: **32018/Z/297/2020.**

I the undersigned Notary in and for the City of Hajdúböszörmény hereby certify that this document on the other side is a true and faithful copy of the document, name of "FREE SALES CERTIFICATE", which bears one signature (which is seemed to be original), one stamp (which is seemed to be original) having been produced to me as original.----------
At **Hajdúböszörmény on the 8th (eighth)** day of **April, 2020 (two thousand and twenty)**. -

dr. Hodosi, Gábor
Civil Law Notary

KÖZJEGYZŐ dr. Hodosi Gábor 1. HAJDÚBÖSZÖRMÉNY

A01/2020/5809
A fenn aláírás és bélyegzőlenyomat
hiteléül.

Budapest, 2020 AUG 0 6.

aláírás

dr. Brezovszki Andrea
jogi előadó

Magyar Országos Közjegyzői Kamara JOGI ELŐADÓ 3.

The Ministry of Foreign Affairs and Trade of Hungary certifies the seal and signature of the **Hungarian Chamber of Civil Law Notaries** appearing on this document.

Legalisation fee paid: 5.500,- HUF
Date: 2020.08.07
Registration nr: 003081/1

Külgazdasági és Külügyminisztérium Ministry of Foreign Affairs and Trade of Hungary 32-4.

dr. Engler Dóra
Head of the Legalisation Unit

Đại sứ quán nước CHXHCN Việt Nam tại CH Hungary

HỢP PHÁP HÓA LÃNH SỰ
Số.1333/LS-HPH
Chứng thực chữ ký của ông/bà
.....Dr. Engler Dóra.....
và con dấu của (cơ quan)
.....Bộ Ngoại giao Hungary.....
Budapest ngày 13/08/2020

ĐSQVN TẠI HUNGARY
TL. ĐẠI SỨ

Bí thư thứ ba
NGUYỄN THÁI HÀ

RUSSIAN
EXPORT CENTER

12, Krasnopresnenskaya nab., Moscow, 123610, Russia, www.exportcenter.ru

CERTIFICATE OF FREE SALE

dated November 06, 2018 No. REC 01/1281/2018

The "Russian Export Center" Joint Stock Company hereby certifies that the following products have passed the state registration in the prescribed manner and were admitted to free distribution on the territory of the Russian Federation.

This Certificate is issued to "Association of Medicine and Analytics" Company Limited ("AMA" Co., Ltd.) for the registration of the following products on the territory of the Socialist Republic of Vietnam

Product names:

1. **HELIC ABT Reader;**
2. **HELIC Ammonia Breath Test (HELIC ABT Reader indicator tube kit).**

Medical Device Certificates of Registration: No. РЗН 2015/2536 dated 09.04.2018; No. ФСР 2009/05180 dated 09.04.2018.

Manufactured by: "Association of Medicine and Analytics" Company Limited, address: 17 line, 4-6, Liter E, Room 1N, 199034, Saint-Petersburg, Russia.

Name and address of the applicant: "Association of Medicine and Analytics" Company Limited, address: 17 line, 4-6, Liter E, Room 1N, 199034, Saint-Petersburg, Russia

(signature)

Senior vice president
I. Zhuk

С 001200

Бюро переводов Guten Morgen®
Группа компаний «Закон есть Закон»®
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Тел. +7 812 579 04 72
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Переведено с английского языка

РОССИЙСКИЙ ЭКСПОРТНЫЙ ЦЕНТР

Россия, Москва, Краснопресненская наб., дом 12, 123610, www.exportcenter.ru

СЕРТИФИКАТ НА СВОБОДНУЮ ПРОДАЖУ
от 06 ноября 2018 года, № РЕК 01/1281/2018

Акционерное общество «Российский экспортный центр» настоящим подтверждает, что следующая продукция прошла государственную регистрацию в установленном порядке и допущена к свободному распространению на территории Российской Федерации.

Настоящий Сертификат выдан ООО «Ассоциация Медицины и Аналитики» (ООО «АМА) для регистрации следующей продукции на территории Социалистической Республики Вьетнам

Наименование продукции:

1. **Система комбинированная ХЕЛИК® -скан-М;**
2. **Аммиачный дыхательный тест ХЕЛИК (Тест-система ХЕЛИК®).**

Свидетельства о регистрации медицинских приборов: № РЗН 2015/2536 от 09.04.2018; № ФСР 2009/05180 от 09.04.2018.

Производитель: ООО «Ассоциация Медицины и Аналитики», адрес: 199034 , Россия, Санкт-Петербург, 17 линия В.О. д. 4-6, литер Е, офис 1Н.

Наименование и адрес заявителя: ООО «Ассоциация Медицины и Аналитики», адрес: 199034 , Россия, Санкт-Петербург, 17 линия В.О. д. 4-6, литер Е, офис 1Н.

/подпись/ Старший вице-президент
(подпись) И. Жук

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АО «Российский экспортный центр»

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Dịch sang tiếng Việt

TRUNG TÂM XUẤT KHẨU LIÊN BANG NGA

Liên Bang Nga, Mátxcơva, Krasnopresnenskaya Nab., số 12. 123610, www.exportcenter.ru

GIẤY CHỨNG NHẬN BÁN HÀNG TỰ DO
Ngày 06 tháng 11 năm 2018, № 01/1281/2018

Công ty cổ phần «Trung tâm xuất khẩu Liên Bang Nga» bằng văn bản này chứng nhận rằng, sản phẩm sau đây đã đăng ký nhà nước theo đúng quy định và được phép lưu hành tự do trên lãnh thổ Liên Bang Nga.

Giấy chứng nhận này được cấp cho Công ty trách nhiệm hữu hạn "Hiệp hội Y học và Phân tích" ("AMA" Co Ltd) đối với việc đăng ký sản phẩm sau đây trên lãnh thổ nước Cộng hòa Xã hội Chủ nghĩa Việt Nam

Tên sản phẩm:

1. **Hệ thống đọc HELIC ABT (HELIC ABT Reader) ;**
2. **Test kiểm tra amoniac trong khí thở (HELIC Ammonia Breath Test; HELIC ABT Reader indicator tube kit).**

Giấy chứng nhận về đăng ý các sản phẩm y tế : № RZN 2015/2536 ngày 09.04.2018; № FCR 2009/05180 ngày 09.04.2018.

Nhà sản xuất: Công ty TNHH "Hiệp hội Y học và Phân tích", địa chỉ 199034, Liên Bang Nga, Sankt-Peterburg, 17 Liniya, 4-6, cổng E, văn phòng 1H

Tên và địa chỉ người nộp đơn: Công ty TNHH "Hiệp hội Y học và Phân tích", địa chỉ 199034, Liên Bang Nga, Sankt-Peterburg, 17 Liniya, 4-6, cổng E, văn phòng 1H

/chữ ký/ Phó chủ tịch
Chữ ký I. Zhuk

Dấu tròn :
Công ty cổ phần «Trung tâm xuất khẩu Liên Bang Nga»
*Liên Bang Nga *Mátxcơva* Số đăng ký nhà nước 1157746363994*
Công ty cổ phần «Trung tâm xuất khẩu Liên Bang Nga»

C 001200

----------*Kết thúc tài liệu dịch*----------

----------*Конец перевода документа*----------

C 001200

Tôi, dịch thuật viên Denis S. Bugaev, thông thạo các ngôn ngữ tiếng Nga, tiếng Việt, tiếng Anh, khẳng định các điều trên là chính xác, cẩn thận và được dịch hoàn thiện từ tài liệu đính kèm.

Я, дипломированный переводчик Бугаев Денис Сергеевич, владеющий русским, вьетнамским и английским языками, подтверждаю, что выполненный мною перевод приложенного документа является правильным, точным и полным.

Dịch thuật viên Denis S. Bugaev
Переводчик Бугаев Денис Сергеевич

01200

САНКТ-

-ПЕТЕРБУРГ

Российская Федерация

Санкт-Петербург

Четырнадцатого декабря две тысячи восемнадцатого года

Я, Бурчалкин Максим Львович, нотариус нотариального округа Санкт-Петербург, свидетельствую подлинность подписи переводчика Бугаева Дениса Сергеевича.

Подпись сделана в моем присутствии.

Личность подписавшего документ установлена.

Зарегистрировано в реестре: № **78/356-н/78-2018-** 41-341

Взыскано государственной пошлины (по тарифу): 100 руб. 00 коп.

Уплачено за оказание услуг правового и технического характера: 200 руб. 00 коп.

М.Л. Бурчалкин

PETERSBURG

Liên Bang Nga

Saint Petersburg.

Ngày 14 tháng 12 năm 2018

Tôi, Burchalkin Maxim Lvovich, công chứng viên tạm thời của phòng công chứng Burchalkin Maxim Lvovich thành phố Saint Petersburg, chứng nhận tính xác thực chữ ký của dịch thuật viên Denis S. Bugaev trong sự có mặt của tôi.

Danh tính của dịch thuật viên ký tài liệu được xác nhận.

Đăng ký vào sổ: № **78/356-n/78-2018-** 41-341.

Chi phí: 100 ruble 00 kopeck

Chi phí cho dịch vụ luật và yếu tố kỹ thuật: 200 ruble 00 kopeck

/Chữ ký/ Burchalkin M.L.

Certified by Saint-Petersburg Chamber of Commerce and Industry
Russia, Saint-Petersburg
ul. Tchaikovskogo, d. 46–48
14.12.2018
E.M. Kruk

Итого в настоящем документе прошито и скреплено печатью 4 (четыре) листа

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/Công chứng M.L. Burchalkin*
Phòng công chứng thành phố: Saint Petersburg*
781005666639/

Document Number : IVXL-FOG6-9G0V-PMEH

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-3775, Fax: +82-43-719-3750

No. of Certificate : 20200093188

Date : 2020/07/27

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country : Vietnam

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 2836)

BEMEMS Co.,Ltd.

Rm703, 706, 709, 710, 711, (Hoseodae Venture Tower, Gasan-dong) 70, Gasan digital 1-ro, Geumcheon-gu, Seoul

Product-License No.	Classification
09-126	X-ray system, diagnostic, portable, analogue [2]
17-4523	X-ray system, diagnostic, portable, analogue [2]
17-4780	X-ray system, diagnostic, mobile, analogue [2]

※Attached : List of Product Classification and Model

Kim youmi

Director of Medical Devices Policy Division
Department of Medical Device Safety Bureau
Ministry of Food and Drug Safety

This medical device is approved by National Institute of Medical Device Safety Information(NIDS) established under
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Document Number : IVXL-FOG6-9G0V-PMEH

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-3775, Fax: +82-43-719-3750

No. of Certificate : 20200093188

Date : 2020/07/27

Product License No. : 09-126 **(2019/02/18)**

Classification : X-ray system, diagnostic, portable, analogue

Model(Export Name)

· BPD-I(수출용)

Product License No. : 17-4523 **(2017/06/30)**

Classification : X-ray system, diagnostic, portable, analogue

Model(Export Name)

· Anyrad-5

Product License No. : 17-4780 **(2019/11/22)**

Classification : X-ray system, diagnostic, mobile, analogue

Model(Export Name)

· AceMobile-510D

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Oh Jung Taek

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深圳市锦瑞生物科技有限公司

深圳国立商事认证中心

证 明 书

CERTIFICATE

中国国际贸易促进委员会暨中国国际商会

China Council for the Promotion of International Trade is China Chamber of International Commerce

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证 明 书
CERTIFICATE

号码 No. 204403A0/036998

兹证明：在所附第粤食药监械出20200899号医疗器械产品出口销售证明上的广东省药品监督管理局的电子印章属实。

THIS IS TO CERTIFY THAT: the electrical seal of MEDICAL PRODUCTS ADMINISTRATION OF GUANGDONG PROVINCE on the CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS NO. YSYJXC 20200899 is genuine.

中国国际贸易促进委员会 CERTIFICATION 商事证明专用章

China Council for the Promotion of International Trade

授权签字：

Authorized Signature: Lai Huilin

日期：2020年07月09日

(Date: Jul. 09, 2020)

证明书查询网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

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兹证明前面文书上中国国际贸易促进委员会商事证明专用章CCPIT（24）的印章和授权签字人**赖慧琳**的签字属实。

中华人民共和国外交部（440）
二〇二〇年七月十四日　广州

00774838

中华人民共和国外交部证件专用章
（440）

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được chứng nhận / hợp pháp hóa lãnh sự / *Certified*

5. tại / *at*: Quảng Châu 6. ngày / *the*: 16 / 07 / 2020

7. Cơ quan cấp / *by*: TLSQ Việt Nam tại Quảng Châu

8. Số / *N°*: 5065 / 2020

Ký tên và đóng dấu / *Signature and seal/stamp*

Lãnh sự

Vũ Hoàng

CHXHCN VIỆT NAM TẠI QUẢNG CHÂU TRUNG QUỐC ★ TỔNG LÃNH SỰ QUÁN

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：粤食药监械出 20200899 号
Certificate NO.：粤食药监械出 20200899 号

产品名称：见附页
Product(s)：See Attachment

规格型号：见附页
Model：See Attachment

产品注册或备案凭证号：见附页
Registration certificate(s)：See Attachment

生产企业：深圳市锘瑞生物科技有限公司
Manufacturer：Genrui Biotech Inc.

生产企业住所：深圳市光明新区马田街道马山头社区钟表基地格雅科技园 3 栋 4 至 10 层
Address of manufacturer：4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

生产许可或备案凭证号：粤食药监械生产许 20041046 号
Manufacturing License(s)：粤食药监械生产许 20041046 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2021 年 04 月 06 日
This certification valid until: 06/04/2021

备注：/
Remark：/

2020 年 06 月 24 日
（出具单位盖章）

广东省药品监督管理局 出口销售证明专用章

医疗器械产品出口销售证明书附页

ATTACHMENT OF CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

出口销售证明专用章

证书编号 Certificate No.：粤食药监械出 20200899 号

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
1	糖化血红蛋白（HbA1c）检测试剂盒（免疫散射比浊法） Glycated Hemoglobin (HbA1c) Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit	粤械注准 20182400309
2	类风湿因子（RF）检测试剂盒（免疫散射比浊法） Rheumatoid Factor (RF) Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、类风湿因子质控品：1×0.2ml（选购） 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.2ml	粤械注准 20182400308
3	尿微量白蛋白（mALB）检测试剂盒（散射比浊法） Human Micro-albuminuria (mALB)Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、尿微量白蛋白质控品：1×0.3ml（选购）。 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.3ml	粤械注准 20162401258
4	超敏 C 反应蛋白（HS—CRP）检测试剂盒（散射比浊法） High Sensitive C-Reactive Protein (HS-CRP) Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、超敏 C 反应蛋白质控品：1×0.2ml（选购）。 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.2m	粤械注准 20162401259
5	纤维蛋白（原）降解产物（FDP）测定试剂盒（免疫散射比浊法） Fibrinogen Degradation Product (FDP) Detection Kit(Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400700

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
6	全自动五分类血液分析仪 Auto Hematology Analyzer	KT—6800 KT—6800	粤械注准 20162400400
7	全自动五分类血液分析仪 Auto Hematology Analyzer	KT—6500、KT—6510、KT—6600、KT—6610 KT-6500、KT-6510、KT-6600、KT-6610	粤械注准 20172400457
8	凝血分析仪 Coagulation Analyzer	CA51、CA52、CA54 CA51、CA52、CA54	粤械注准 20162400480
9	尿液化学分析仪 Urine Analyzer	BA600、BA600-1、BA600-2 BA600、BA600-1、BA600-2	粤械注准 20162400479
10	尿液化学分析仪 Urine Analyzer	BA660、BA670、BA680 BA660、BA670、BA680	粤械注准 20162400669
11	特定蛋白分析仪 Specific Protein Analyzer	PA50、PA54 PA50、PA54	粤械注准 20162400696
12	全自动特定蛋白分析仪 Fully-auto Specific Protein Analyzer	PA120、PA200、PA300、PA320 PA120、PA200	粤械注准 20172401577
13	荧光免疫分析仪 Quantitative Immunoassay Analyzer	FA50、FA51、FA52、FA53、FA54、FA120 FA50、FA51、FA52、FA53、FA54、FA120	粤械注准 20152220431
14	电解质分析仪 Electrolyte Analyzer	GE200、GE300、GE310、GE320、GE330、GE340、GE350、GE360 GE200、GE300、GE310、GE320、GE330、GE340、GE350、GE360	粤械注准 20162400668
15	电解质分析仪 Electrolyte Analyzer	GE500、GE510、GE520、GE530、GE540、GE550 GE500、GE510、GE520、GE530、GE540、GE550	粤械注准 20152220120
16	半自动生化分析仪 Semi-auto Chemistry Analyzer	WP21A、WP21B、WP21C、WP21D、WP21E WP21A、WP21B、WP21C、WP21D、WP21E	粤械注准 20162400481
17	全自动生化分析仪 Auto Chemistry Analyzer	GS480Plus、GS480、GS400、GS300Plus、GS300、GS200、GS480A、GS450A、GS450 GS480Plus、GS480、GS400、GS300Plus、GS300、GS200、GS480A、GS450A、GS450	粤械注准 20162400670

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
18	全自动化学发光免疫分析仪 Chemiluminescence Immunoassay Analyzer	MT120、MT120S MT120、MT120S	粤械注准 20182400240
19	尿液分析试纸条 Urine Strip	型号:BA-10A、BA-10EA、BA-10B、BA-10C、BA-10D、BA-10G、BA-10F、BA-10T、BA-11A、BA-11B、BA-11C、BA-11D、BA-11T、BA-11F、BA-11G、BA-11HK、BA-11BH、BA-11BU、BA-12A、BA12-B、BA-14A、BA-14B、BA-14C、BA-14D；规格：1条装，30条/筒，50条/筒，100条/筒。 BA-11A、BA-11B、BA-11C、BA-11D、BA-11T、BA-11F、BA-11G、BA-11HK、BA-11BH、BA-11BU、BA-10A、BA-10EA、BA-10B、BA-10C、BA-10D、BA-10G、BA-10F、BA-10T、BA-8A、BA-8V、BA-8C、BA-8D	粤械注准 20152400734
20	抗链球菌溶血素O（ASO）检测试剂盒（免疫散射比浊法） Anti-streptolysin O (ASO) Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、抗链球菌溶血素O质控品：1×0.2mL（选购） 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.2ml	粤械注准 20182400305
21	抗环瓜氨酸肽抗体（CCP）检测试剂盒（免疫散射比浊法） Anticyclic Citrullinated Peptide Antibody (CCP) Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、抗环瓜氨酸肽抗体质控品：1×0.2ml（选购） 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.2ml	粤械注准 20182400087
22	胱氨酸蛋白酶抑制剂C（CYS—C）检测试剂盒（免疫散射比浊法） Cystatin C (CYS-C) Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、胱氨酸蛋白酶抑制剂C质控品：1×0.2ml（选购） 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.2ml	粤械注准 20182400307
23	D—二聚体（D—Dimer）检测试剂盒（免疫散射比浊法） D-Dimer Detection Kit(Nephelometry)	25T/盒、50T/盒、100T/盒、150T/盒、200T/盒、250T/盒、300T/盒、D-二聚体质控品：1×0.2ml（选购） 25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、250 T/Kit、300 T/Kit、Quality control product 1×0.2ml	粤械注准 20182400306
24	全自动血细胞分析仪	KT-6300、KT-6280、KT-6200、KT-	粤械注准 20162400482

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
	Auto Hematology Analyzer	6180 KT-6300、KT-6280、KT-6200、KT-6180	
25	全自动血细胞分析仪 Auto Hematology Analyzer	KT-6400、KT-6390、KT-6380、KT-6370、KT-6360 KT-6400、KT-6390、KT-6380、KT-6370、KT-6360	粤械注准 20162400666
26	视黄醇结合蛋白（RBP）测定试剂盒（免疫散射比浊法） Retinol Binding Protein (RBP) Detection Kit(Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400705
27	中性粒细胞明胶酶相关脂质运载蛋白（NGAL）测定试剂盒（免疫散射比浊法） Neutrophil Gelatinase-associated Lipocalin (NGAL) Detection Kit(Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400704
28	血清淀粉样蛋白 A（SAA）测定试剂盒（免疫散射比浊法） Serum Amyloid Protein A (SAA) Detection Kit(Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400563
29	免疫球蛋白 G（IgG）测定试剂盒（免疫散射比浊法） Immunoglobulin G (IgG) Detection Kit (Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400669
30	高密度脂蛋白胆固醇（HDL—C）测定试剂盒（选择性抑制法） HDL-CReagentKit(SelectInhibitionMethod)	20mL(R1： 1×15ml R2：1×5ml)、80mL(R1： 2×30ml R2：2×10ml)、120mL(R1： 2×45 ml R2： 3×10ml)、200mL(R1：3×50ml R2：2×25ml)、320mL(R1： 6×40ml R2： 4×20ml) 20ml (R1:1×15ml R2:1×5ml) 80ml (R1:2×30ml R2:2×10ml) 120ml (R1:2×45ml R2:3×10ml) 200ml (R1:3×50ml R2:2×25ml) 320ml (R1:6×40ml R2:4×20ml)	粤械注准 20162400562

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
31	白蛋白（ALB）测定试剂盒（溴甲酚绿法） ALB Reagent Kit(BCG Colorimetric Method)	20mL(1×20ml)、100mL(2×50ml)、200mL(5×40ml)、300mL(6×50ml)、350mL(5×70ml)、500mL(10×50ml) 20ml (1×20ml) 100ml (2×50ml) 200ml (5×40ml) 300ml (6×50ml) 350ml (5×70ml) 500ml (10×50ml)	粤械注准 20162400569
32	尿酸（UA）测定试剂盒（尿酸酶—过氧化物酶偶联法） UA Reagent Kit(Uricase-Peroxidase Coupling Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400543
33	肌酸激酶（CK）测定试剂盒（N—乙酰半胱氨酸法） CK Reagent Kit(NAC Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400556
34	γ—谷氨酰基转移酶（GGT）测定试剂盒（IFCC 推荐法） GGT Reagent Kit(IFCC Kinetic Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml)	粤械注准 20162400578

出口销售证明专用章

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		500ml (R1:8×50ml R2:4×25ml)	
35	尿素 （UREA）测定试剂盒（酶偶联速率法） UREA Reagent Kit(Enzyme-coupling Kinetic Method)	25mL (R1:1×20 mL、R2:1×5 mL)、125mL(R1:2×50 mL、R2:1×25 mL)、200mL(R1:4×40 mL、R2:2×20 mL)、250mL(R1:4×50 mL、R2:2×25 mL)、300mL(R1:4×60 mL、R2:4×15 mL)、375mL(R1:6×50 mL、R2:3×25 mL)、500mL(R1:8×50 mL、R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400557
36	胱抑素 C（Cys—C）测定试剂盒（免疫比浊法） Cystatin C (Cys-C) Reagent Kit (Immunoturbidimetry)	R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：1×80 ml R2：1×20 ml、R1：2×40 ml R2：2×10 ml、R1：2×60 ml R2：1×30 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：1×40 ml、R1：2×80 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml、R1：4×60 ml R2：2×30 ml、R1：4×100 ml R2：2×50 ml、校准品：1×1 ml（可选购）、质控品（低值）：1×1 ml（可选购）、质控品（高值）：1×1 ml（可选购） R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：1×80 ml R2：1×20 ml、R1：2×40 ml R2：2×10 ml、R1：2×60 ml R2：1×30 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：1×40 ml、R1：2×80 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml、R1：4×60 ml R2：2×30 ml、R1：4×100 ml R2：2×50 ml、Calibrator：1×1 ml、Quality control product（low value）：1×1 ml、Quality control product（High value）：1×1 ml	粤械注准 20172401005
37	抗环瓜氨酸肽抗体（Anti—CCP）测定试剂盒（免疫比浊法） Anti-cyclic Citrullinated Peptide Antibody (Anti-CCP) Reagent Kit (Immunoturbidimetry)	R1：1×15 ml R2：1×5 ml、R1：1×30 ml R2：1×10 ml、R1：1×45 ml R2：1×15 ml、R1：2×60 ml R2：2×20 ml、R1：3×40 ml R2：2×20 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购）； R1：1×15 ml R2：1×5 ml、R1：1×30 ml R2：1×10 ml、R1：1×45 ml R2：1×15 ml、R1：2×60 ml R2：2×20 ml、R1：3×40 ml R2：2×20 ml、Calibrator：1×1 ml、Quality	粤械注准 20172401274

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		control product：1×1 ml	
38	抗链球菌溶血素O（ASO）测定试剂盒（免疫比浊法） Antistreptolysin O (ASO) Reagent Kit (Immunoturbidimetry)	R1: 1×20 ml R2: 1×5 ml、R1: 1×40 ml R2: 1×10 ml、R1: 1×80 ml R2: 1×20 ml、R1: 2×40 ml R2: 2×10 ml、R1: 2×60 ml R2: 2×15 ml、R1: 2×60 ml R2: 1×30 ml、R1: 2×80 ml R2: 1×40 ml、R1: 2×80 ml R2: 2×20 ml、R1: 4×50 ml R2: 2×25 ml、R1: 4×60 ml R2: 2×30 ml、R1: 4×100 ml R2: 2×50 ml、校准品：1×1 ml（可选购）、质控品（低值）：1×1 ml（可选购）、质控品（高值）：1×1 ml（可选购） R1: 1×20 ml R2: 1×5 ml、R1: 1×40 ml R2: 1×10 ml、R1: 1×80 ml R2: 1×20 ml、R1: 2×40 ml R2: 2×10 ml、R1: 2×60 ml R2: 2×15 ml、R1: 2×60 ml R2: 1×30 ml、R1: 2×80 ml R2: 1×40 ml、R1: 2×80 ml R2: 2×20 ml、R1: 4×50 ml R2: 2×25 ml、R1: 4×60 ml R2: 2×30 ml、R1: 4×100 ml R2: 2×50 ml、Calibrator：1×1 ml、Quality control product（low value）：1×1 ml、Quality control product（High value）：1×1 ml	粤械注准 20172401276
39	类风湿因子（RF）测定试剂盒（免疫比浊法） Rheumatoid Factor (RF) Reagent Kit (Immunoturbidimetry)	R1: 1×20 ml R2: 1×5 ml、R1: 1×40 ml R2: 1×10 ml、R1: 2×40 ml R2: 2×10 ml、R1: 2×60 ml R2: 1×30 ml、R1: 2×80 ml R2: 1×40 ml、R1: 4×50 ml R2: 2×25 ml、校准品：1×1 ml（可选购） R1: 1×20 ml R2: 1×5 ml、R1: 1×40 ml R2: 1×10 ml、R1: 2×40 ml R2: 2×10 ml、R1: 2×60 ml R2: 1×30 ml、R1: 2×80 ml R2: 1×40 ml、R1: 4×50 ml R2: 2×25 ml、Calibrator：1×1 ml	粤械注准 20172401278
40	尿微量白蛋白（mALB）测定试剂盒（免疫比浊法） Microalbumin (mALB) Reagent Kit (Immunoturbidimetry)	R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：2×60 ml R2：2×20 ml、R1：3×50 ml R2：2×25 ml、R1：3×60 ml R2：2×30 ml、R1：3×80 ml R2：1×80 ml、R1：3×100 ml R2：1×100 ml、校准品：1×1 ml（可选购）； R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：2×60 ml R2：2×20 ml、R1：3×50 ml R2：2×25 ml、R1：3×60 ml R2：2×30 ml、R1：3×80 ml R2：1×80 ml、R1：3×100 ml R2：1×100 ml、Calibrator：1×1 ml	粤械注准 20172402010

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
41	人血浆脂蛋白磷脂酶 A2（Lp—PLA2）测定试剂盒（免疫比浊法） Human Plasma Lipoprotein Phospholipase A2 (Lp-PLA2) Reagent Kit (Immunoturbidimetry)	R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：2×30 ml R2：1×20 ml、R1：2×60 ml R2：2×15 ml、R1：4×40 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：2×30 ml R2：1×20 ml、R1：2×60 ml R2：2×15 ml、R1：4×40 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml	粤械注准 20172400889
42	视黄醇结合蛋白（RBP）测定试剂盒（免疫比浊法） Retinol Binding Protein (RBP) Reagent Kit (Immunoturbidimetry)	R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：4×45 ml R2：3×20 ml、R1：8×45 ml R2：6×20 ml、R1：12×40 ml R2：8×20 ml、校准品：1×1ml （可选购）。 R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：4×45 ml R2：3×20 ml、R1：8×45 ml R2：6×20 ml、R1：12×40 ml R2：8×20 ml、Calibrator：1×1ml	粤械注准 20172400917
43	葡萄糖（GLU）测定试剂盒（葡萄糖氧化酶法） GLU Reagent Kit(Glucose Oxidase Method)	20mL(1×20ml)、100mL(2×50ml)、200mL(5×40ml)、300mL(6×50ml)、350mL(5×70ml)、500mL(10×50ml) 20ml (1×20ml) 100ml (2×50ml) 200ml (5×40ml) 300ml (6×50ml) 350ml (5×70ml) 500ml (10×50ml)	粤械注准 20162400564
44	二氧化碳（CO2）测定试剂盒（酶法） CO2 Reagent Kit(Enzymatic Method)	20mL(1×20ml)、80mL(2×40ml)、150mL(3×50ml)、300mL(5×60ml) 20ml (1×20ml) 80ml (2×40ml) 150ml (3×50ml) 300ml (5×60ml)	粤械注准 20162400559
45	乳酸脱氢酶（LDH）测定试剂盒（乳酸→丙酮酸连续监测法） LDH Reagent Kit(L→P Kinetic Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml)	粤械注准 20162400570

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		500ml (R1:8×50ml R2:4×25ml)	
46	甘油三酯（TG）测定试剂盒（GPO—PAP 法） TG Reagent Kit (GPO-PAP Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400545
47	天门冬氨酸氨基转移酶（AST）测定试剂盒（IFCC 推荐法） AST Reagent Kit(IFCC Kinetic Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL)。 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400567
48	碱性磷酸酶（ALP）测定试剂盒（IFCC 推荐法） ALP Reagent Kit(IFCC Kinetic Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400560
49	总胆固醇（CHOL）测定试剂盒（COD—PAP 法） CHOL Reagent Kit(COD-PAP Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25	粤械注准 20162400561

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		mL） 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	
50	总胆红素（T—BIL）测定试剂盒（化学氧化法） T-BIL Reagent Kit(Vanadate Oxidation Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400573
51	丙氨酸氨基转移酶（ALT）测定试剂盒（IFCC 推荐法） ALT Reagent Kit(IFCC Kinetic Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400553
52	糖化白蛋白比值测定试剂盒（酶法） Glycated Albumin (GA) Reagent Kit (Enzymatic Method)	R1：1×20 ml R2：1×5 ml R3：1×30 ml；R1：1×40 ml R2：1×10 ml R3：2×30 ml；R1：2×40 ml R2：2×10 ml R3：3×40 ml；R1：1×80 ml R2：1×20 ml R3：2×60 ml；糖化白蛋白校准品：1×1 ml（可选购）、白蛋白校准品：1×1 ml（可选购）、糖化白蛋白质控品：1×1 ml（可选购） R1：1×20 ml R2：1×5 ml R3：1×30 ml；R1：1×40 ml R2：1×10 ml R3：2×30 ml；R1：2×40 ml R2：2×10 ml R3：3×40 ml；R1：1×80 ml R2：1×20 ml R3：2×60 ml、Glycated albumin calibrator.：1×1	粤械注准 20172402008

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		ml、Albumin calibrator：1×1 ml、Glycosylated albumin quality control product：1×1 ml	
53	铁（Fe）测定试剂盒（亚铁嗪比色法） Iron (Fe) Reagent Kit (Ferrozine Colorimetric Method)	R1：1×20 ml R2：1×10 ml、R1：2×40 ml R2：2×20 ml、R1：2×50 ml R2：1×50 ml、R1：2×70 ml R2：1×70 ml、R1：2×80 ml R2：1×80 ml、R1：4×50 ml R2：2×50 ml、R1：4×70 ml R2：2×70 ml、R1：4×100 ml R2：2×100 ml、校准品：1×1 ml（可选购）。 R1：1×20 ml R2：1×10 ml、R1：2×40 ml R2：2×20 ml、R1：2×50 ml R2：1×50 ml、R1：2×70 ml R2：1×70 ml、R1：2×80 ml R2：1×80 ml、R1：4×50 ml R2：2×50 ml、R1：4×70 ml R2：2×70 ml、R1：4×100 ml R2：2×100 ml、Calibrator：1×1 ml	粤械注准 20172400882
54	免疫球蛋白 M（IgM）测定试剂盒（免疫散射比浊法） Immunoglobulin M (IgM) Detection Kit (Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400673
55	胃蛋白酶原 I（PGI）测定试剂盒（免疫散射比浊法） Pepsinogen I (PGI) Detection Kit (Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400701
56	唾液酸（SA）测定试剂盒（酶法） Sialic Acid (SA) Reagent Kit (Enzymatic Method)	R1：1×15 ml R2：1×5 ml、R1：1×30 ml R2：1×10 ml、R1：1×45 ml R2：1×15 ml、R1：2×30 ml R2：2×10 ml、R1：2×60 ml R2：2×20 ml、R1：3×40 ml R2：2×20 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购）。 R1：1×15 ml R2：1×5 ml、R1：1×30 ml R2：1×10 ml、R1：1×45 ml R2：1×15 ml、R1：2×30 ml R2：2×10 ml、R1：2×60 ml R2：2×20 ml、R1：3×40 ml R2：2×20 ml、Calibrator：1×1 ml、Quality control product：1×1 ml	粤械注准 20172402009
57	血清淀粉样蛋白 A（SAA）测定试剂盒（免疫比浊法） Serum Amyloid Protein A (SAA) Reagent Kit (Immunoturbidimetry)	R1：1×25 ml R2：1×5 ml、R1：1×50 ml R2：1×10 ml、R1：2×50 ml R2：1×20 ml、R1：3×50 ml R2：2×15 ml、R1：4×50 ml R2：2×20 ml、校准品：1×1 ml(可选购)	粤械注准 20172401273

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		R1：1×25 ml R2：1×5 ml、R1：1×50 ml R2：1×10 ml、R1：2×50 ml R2：1×20 ml、R1：3×50 ml R2：2×15 ml、R1：4×50 ml R2：2×20 ml、Calibrator：1×1 ml	
58	游离脂肪酸（NEFA）测定试剂盒（酶比色法） Non-esterified Fatty Acid (NEFA) Reagent Kit (Enzymatic Colorimetric Method)	R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：1×80 ml R2：1×20 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购）。 R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：1×80 ml R2：1×20 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml、Calibrator：1×1 ml、Quality control product：1×1 ml	粤械注准 20172400891
59	中性粒细胞明胶酶相关脂质运载蛋白（NGAL）测定试剂盒（免疫比浊法） Neutrophil Gelatinase-associated Lipocalin (NGAL) Reagent Kit (Immunoturbidimetry)	R1：1×20 ml R2：1×5 ml、R1：1×48 ml R2：1×12 ml、R1：2×40 ml R2：1×20 ml、R1：3×40 ml R2：2×15 ml、R1：2×60 ml R2：2×15 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购）。 R1：1×20 ml R2：1×5 ml、R1：1×48 ml R2：1×12 ml、R1：2×40 ml R2：1×20 ml、R1：3×40 ml R2：2×15 ml、R1：2×60 ml R2：2×15 ml、Calibrator：1×1 ml、Quality control product：1×1 ml	粤械注准 20172400890
60	转铁蛋白（TRF）测定试剂盒（免疫比浊法） Transferrin (TRF) Reagent Kit (Immunoturbidimetry)	R1：1×20 ml R2：1×5 ml、R1：1×48 ml R2：1×12 ml、R1：3×40 ml R2：2×15 ml、校准品：1×1 ml（可选购）、质控品（低值）：1×1 ml（可选购）、质控品（高值）：1×1 ml（可选购）。 R1：1×20 ml R2：1×5 ml、R1：1×48 ml R2：1×12 ml、R1：3×40 ml R2：2×15 ml、Calibrator：1×1 ml、Quality control product（Low value）：1×1 ml、Quality control product（High value）：1×1 ml	粤械注准 20172400883
61	腺苷脱氨酶（ADA）测定试剂盒（酶比色法） Adenosine Deaminase (ADA) Reagent kit (Enzymatic Colorimetric Method)	R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：2×60 ml R2：2×20 ml、R1：3×50 ml R2：2×25 ml、R1：3×60 ml R2：2×30 ml、R1：3×80 ml R2：1×80 ml、R1：3×100 ml R2：1×100 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购）。 R1：1×15 ml R2：1×5 ml、R1：	粤械注准 20172400884

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：2×60 ml R2：2×20 ml、R1：3×50 ml R2：2×25 ml、R1：3×60 ml R2：2×30 ml、R1：3×80 ml R2：1×80 ml、R1：3×100 ml R2：1×100 ml、Calibrator：1×1 ml、Quality control product：1×1 ml	
62	5'—核苷酸酶（5'—NT）测定试剂盒（酶比色法） 5'-Nucleotidase (5'-NT) Reagent kit (Enzymatic Colorimetric Method)	R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：2×60 ml R2：2×20 ml、R1：3×50 ml R2：2×25 ml、R1：3×60 ml R2：2×30 ml、R1：3×80 ml R2：1×80 ml、R1：3×100 ml R2：1×100 ml、校准品：1×1 ml（可选购）、质控品（低值）：1×1 ml（可选购）、质控品（高值）：1×1 ml（可选购）。 R1：1×15 ml R2：1×5 ml、R1：2×30 ml R2：1×20 ml、R1：2×45 ml R2：2×15 ml、R1：3×40 ml R2：2×20 ml、R1：2×60 ml R2：2×20 ml、R1：3×50 ml R2：2×25 ml、R1：3×60 ml R2：2×30 ml、R1：3×80 ml R2：1×80 ml、R1：3×100 ml R2：1×100 ml、Calibrator：1×1 ml、Quality control product（low value）：1×1 ml、Quality control product（High value）：1×1 ml	粤械注准 20172400886
63	葡萄糖（GLU）测定试剂盒（己糖激酶法） GLU Reagent Kit(Hexokinase Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400587
64	肌酐（CREA）测定试剂盒（肌氨酸氧化酶法） CREA Reagent Kit(Sarcosine Oxidase Method)	20mL(R1： 15ml×1 R2：5ml×1)、80mL(R1： 2×30ml R2：2×10ml)、120mL(R1： 2×45 ml R2： 3×10ml)、200mL(R1：3×50ml R2：2×25ml)、320mL(R1： 6×40ml R2： 4×20ml)	粤械注准 20162400566

出口销售证明专用章

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		20ml (R1:1×15ml R2:1×5ml) 80ml (R1:2×30ml R2:2×10ml) 120ml (R1:2×45ml R2:3×10ml) 200ml (R1:3×50ml R2:2×25ml) 320ml (R1:6×40ml R2:4×20ml)	
65	总蛋白（TP）测定试剂盒（双缩脲比吸光度法） TP Reagent Kit(Biuret Colorimetric Method)	20mL(1×20ml)、100mL(2×50ml)、200mL(5×40ml)、300mL(6×50ml)、350mL(5×70ml)、500mL(10×50ml) 20ml (1×20ml) 100ml (2×50ml) 200ml (5×40ml) 300ml (6×50ml) 350ml (5×70ml 500ml (10×50ml)	粤械注准 20162400552
66	胆碱脂酶（CHE）测定试剂盒（速率法） CHE Reagent Kit(Kinetic Method)	25mL(R1：1×20ml R2：1×5ml)、50mL(R1：1×40ml R2：1×10ml)、125mL(R1：2×50ml R2：1×25ml)、300mL(R1：4×60ml R2：3×20ml) 25ml (R1:1×20ml R2:1×5ml) 50ml (R1:1×40ml R2:1×10ml) 125ml (R1:2×50ml R2:1×25ml) 300ml (R1:4×60ml R2:3×20ml)	粤械注准 20162400575
67	直接胆红素（D—BIL）测定试剂盒（化学氧化法） D-BIL Reagent Kit(Vanadate Oxidation Method)	25mL (R1:1×20 mL R2:1×5 mL)、125mL(R1:2×50 mL R2:1×25 mL)、200mL(R1:4×40 mL R2:2×20 mL)、250mL(R1:4×50 mL R2:2×25 mL)、300mL(R1:4×60 mL R2:4×15 mL)、375mL(R1:6×50 mL R2:3×25 mL)、500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400563
68	低密度脂蛋白胆固醇（LDL—C）测定试剂盒（直接测定法） LDL-C Reagent Kit(Direct Method)	20mL(R1：1×15ml R2：1×5ml)、80mL(R1：2×30ml R2：2×10ml)、120mL(R1：2×45ml R2：3×10ml)、200mL(R1：3×50ml R2：2×25ml)、320mL(R1：6×40ml R2：4×20ml) 20ml (R1:1×15ml R2:1×5ml) 80ml (R1:2×30ml R2:2×10ml) 120ml (R1:2×45ml R2:3×10ml) 200ml (R1:3×50ml R2:2×25ml) 320ml (R1:6×40ml R2:4×20ml)	粤械注准 20162400568

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
69	α—淀粉酶（AMY）测定试剂盒（IFCC 推荐法） AMY Reagent Kit(IFCC Kinetic Method)	25mL(R1：20ml×1 R2：5ml)、50mL(R1：1×40ml R2：10ml)、125mL(R1：2×50ml R2：1×25ml)、300mL(R1:4×60ml R2:3×20ml) 25ml (R1:1×20ml R2:1×5ml) 50ml (R1:1×40ml R2:1×10ml) 125ml (R1:2×50ml R2:1×25ml) 300ml (R1:4×60ml R2:3×20ml)	粤械注准 20162400546
70	同型半胱氨酸（HCY）测定试剂盒（循环酶法） HCY Reagent Kit(Enzymatic Cycling Method)	22mL(R1：1×20ml R2：1×2ml)、44mL(R1：1×40ml R2：1×4ml)、55mL(R1：1×50ml R2：1×5ml)、110mL(R1：2×50ml R2：1×10ml) 22ml (R1:1×20ml R2:1×2ml) 44ml (R1:1×40ml R2:1×4ml) 55ml (R1:1×50ml R2:1×5ml) 110ml (R1:2×50ml R2:1×10ml)	粤械注准 20162400576
71	β2—微球蛋白（β2—MG）测定试剂盒（免疫散射比浊法） β2-Microglobulin (β2-MG) Detection Kit(Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400706
72	免疫球蛋白 A（IgA）测定试剂盒（免疫散射比浊法） Immunoglobulin A (IgA) Detection Kit (Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400670
73	人血浆脂蛋白磷脂酶 A2（Lp—PLA2）测定试剂盒（免疫散射比浊法） Human Plasma Lipoprotein Phospholipase A2 (Lp-PLA2) Detection Kit (Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400676
74	心脏型脂肪酸结合蛋白（H—FABP）测定试剂盒（免疫散射比浊法） Heart Fatty Acid Binding Protein (H-FABP) Detection Kit (Nephelometry)	25 人份/盒、2×15 人份/盒、2×25 人份/盒、50 人份/盒、100 人份/盒、150 人份/盒、200 人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400674
75	β2—微球蛋白（β2—MG）测定试	R1：1×20 ml R2：1×5 ml、R1：	粤械注准 20172400885

出口销售证明专用章

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
	剂盒（免疫比浊法） β2-Microglobulin (β2-MG) Reagent Kit (Immunoturbidimetry)	1×40 ml R2：1×10 ml、R1：1×30 ml R2：1×20 ml、R1：2×40 ml R2：2×10 ml、R1：2×60 ml R2：1×30 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：2×20 ml、R1：2×80 ml R2：1×40 ml、R1：4×50 ml R2：2×25 ml、R1：4×60 ml R2：2×30 ml、R1：4×100 ml R2：2×50 ml、校准品：1×1 ml（可选购）、质控品（低值）：1×1 ml（可选购）、质控品（高值）：1×1 ml（可选购）。 R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：1×80 ml R2：1×20 ml、R1：2×40 ml R2：2×10 ml、R1：2×60 ml R2：1×30 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：2×20 ml、R1：2×80 ml R2：1×40 ml、R1：4×50 ml R2：2×25 ml、R1：4×60 ml R2：2×30 ml、R1：4×100 ml R2：2×50 ml、Calibrator：1×1 ml、Quality control product (low value):1×1 ml、Quality control product(High value):1×1 ml	
76	C 反应蛋白（CRP）测定试剂盒（免疫比浊法） C-Reactive Protein (CRP) Reagent Kit (Immunoturbidimetry)	R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：2×30 ml R2：1×15 ml、R1：2×40 ml R2：1×20 ml、R1：2×60 ml R2：2×15 ml、R1：4×40 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml、R1：4×80 ml R2：2×40 ml、校准品：1×1 ml（可选购）； R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：2×30 ml R2：1×15 ml、R1：2×40 ml R2：1×20 ml、R1：2×60 ml R2：2×15 ml、R1：4×40 ml R2：2×20 ml、R1：4×50 ml R2：2×25 ml、R1：4×80 ml R2：2×40 ml、Calibrator：1×1 ml	粤械注准 20172402011
77	超氧化物歧化酶（SOD）测定试剂盒（比色法） Superoxide Dismutase (SOD) Reagent kit (Colorimetric Method)	R1：1×15 ml R2：1×5 ml、R1：1×30 ml R2：1×10 ml、R1：1×45 ml R2：1×15 ml、R1：2×60 ml R2：2×20 ml、R1：3×40 ml R2：2×20 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购） R1：1×15 ml R2：1×5 ml、R1：1×30 ml R2：1×10 ml、R1：1×45 ml R2：1×15 ml、R1：2×60 ml R2：2×20 ml、R1：3×40 ml R2：2×20 ml、Calibrator：1×1 ml、Quality control product：1×1 ml	粤械注准 20172401275
78	甘胆酸（CG）测定试剂盒（均相酶免法）	R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：2×60 ml	粤械注准 20172400916

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
	Glycocholic Acid (CG) Reagent kit (Homogeneous Enzyme Immunoassay)	R2：2×15 ml、R1：2×80 ml R2：2×20 ml、R1：4×40 ml R2：2×20 ml、校准品：1×1 ml（可选购）、质控品：1×1 ml（可选购）。 R1：1×20 ml R2：1×5 ml、R1：1×40 ml R2：1×10 ml、R1：2×60 ml R2：2×15 ml、R1：2×80 ml R2：2×20 ml、R1：4×40 ml R2：2×20 ml、Calibrator：1×1 ml、Quality control product：1×1 ml	
79	全量程C反应蛋白（hs—CRP+常规CRP）测定试剂盒（免疫散射比浊法） C-Reactive Protein (CRP) Detection Kit(Nephelometry)	25人份/盒、2×15人份/盒、2×25人份/盒、50人份/盒、100人份/盒、200人份/盒、300人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、200 T/Kit、300T/Kit、Quality control product 1×0.2ml	粤械注准20192401024
80	补体C3（C3）测定试剂盒（免疫散射比浊法） Complement C3 (C3) Detection Kit (Nephelometry)	25人份/盒、2×15人份/盒、2×25人份/盒、50人份/盒、100人份/盒、150人份/盒、200人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400671
81	补体C4（C4）测定试剂盒（免疫散射比浊法） Complement C4 (C4) Detection Kit (Nephelometry)	25人份/盒、2×15人份/盒、2×25人份/盒、50人份/盒、100人份/盒、150人份/盒、200人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400675
82	胃蛋白酶原II（PGII）测定试剂盒（免疫散射比浊法） Pepsinogen II (PGII) Detection Kit (Nephelometry)	25人份/盒、2×15人份/盒、2×25人份/盒、50人份/盒、100人份/盒、150人份/盒、200人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400672
83	转铁蛋白（TRF）测定试剂盒（免疫散射比浊法） Transferrin (TRF) Detection Kit (Nephelometry)	25人份/盒、2×15人份/盒、2×25人份/盒、50人份/盒、100人份/盒、150人份/盒、200人份/盒、质控品：1×0.2ml（选购） 25 T/Kit、2×15 T/Kit、2×25 T/Kit、50 T/Kit、100 T/Kit、150 T/Kit、200 T/Kit、Quality control product 1×0.2ml	粤械注准 20172400703
84	D—二聚体（D—Dimer）测定试剂盒（荧光免疫层析法）	1人份/盒、10人份/盒、25人份/盒、50人份/盒、100人份/盒、质控品（选购）（水平1：0.5mL×1瓶	粤械注准 20192400429

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
	D-Dimer Test Kit(Immunofluorescence)	水平 2：0.5mL×1 瓶 水平 3：0.5mL×1 瓶） 1T/Kit、10T/Kit、25 T/Kit、50 T/Kit、100 T/Kit、 Quality control product, level 1: 1×0.5ml, level 2: 1×0.5ml, level 3: 1×0.5ml	
85	糖化血红蛋白（HbAlc）测定试剂盒（荧光免疫层析法） Glycated Hemoglobin (HbA1c) Test Kit(Immunofluorescence)	1 人份/盒、10 人份/盒、25 人份/盒、50 人份/盒、100 人份/盒、质控品（选购）（水平 1：0.5mL×1 瓶、水平 2：0.5mL×1 瓶、水平 3：0.5mL×1 瓶）。 1T/Kit、10T/Kit、25 T/Kit、50 T/Kit、100 T/Kit、 Quality control product, level 1: 1×0.5ml, level 2: 1×0.5ml, level 3: 1×0.5ml	粤械注准 20192400981
86	肌酸激酶 MB 型同工酶（CK—MB）测定试剂盒（免疫抑制法） CK-MB Reagent Kit(Immunity Repression Method)	25mL (R1:1×20 mL R2:1×5 mL)； 125mL(R1:2×50 mL R2:1×25 mL)； 200mL(R1:4×40 mL R2:2×20 mL)； 250mL(R1:4×50 mL R2:2×25 mL)； 300mL(R1:4×60 mL R2:4×15 mL)； 375mL(R1:6×50 mL R2:3×25 mL)； 500mL(R1:8×50 mL R2:4×25 mL) 25ml (R1:1×20ml R2:1×5ml) 125ml (R1:2×50ml R2:1×25ml) 200ml (R1:4×40ml R2:2×20ml) 250ml (R1:4×50ml R2:2×25ml) 300ml (R1:4×60ml R2:4×15ml) 375ml (R1:6×50ml R2:3×25ml) 500ml (R1:8×50ml R2:4×25ml)	粤械注准 20162400554
/	/	/	/

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GOVERNMENT OF INDIA
DEPARTMENT OF COMMERCE
OFFICE OF THE ADDITIONAL DIRECTOR GENERAL OF FOREIGN TRADE.
NISHTA BHAWAN, 48, VITHALDAS THAKERSEY MARG, NEW MARINE LINES,CHURCHGATE, MUM- 20.

File No. 03/27/108/00107/AM-20 **Date: 11.06.2019**

FORWARDING LETTER

To,
M/s. PHILIPS INDIA LTD
7, JUSTICE CHANDRA MADHAB ROAD
KOLKATA, WEST BENGAL
PIN-700020.

SUB: Grant of Free Sale and Commerce Certificate During the period: Calendar year AM-20.

Gentleman,

With reference to your application dated 04.06.2019 on the above subject, I am forwarding herewith the Free Sale and Commerce Certificate.

NOTARY PUBLIC ASHOK KUMAR ADVOCATE L.No. 4449 GOVT. OF INDIA

(Avil Dmello)
ASST.Director General of Foreign Trade.
For Additional Director General of Foreign Trade.

Encl: Free Sale and Commerce Certificate.

File No. 03/27/108/0107/AM-20 Date: 11.06.2019

Copy forwarded to O/o. Director General of Foreign Trade, New Delhi, with reference to their Endt: Public Notice No. 64/2009-14 dated: 18.05.2010 read with para 2.49 (b) (i) & (b) (ii) of H. B.P. 2009-2014 (updated as on 05.06.2012), .and copy forwarded to Director General of Health Services

Encl: Free Sale and Commerce Certificate

PHILIPS INDIA LIMITED

C27074

PHD Chamber of Commerce and Industry - 4 SEP 2019 New Delhi-110 001

ATTESTED
Gur Singh Dharwal
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

GOVERNMENT OF INDIA
MINISTRY OF COMMERCE AND INDUSTRY
DEPARTMENT OF COMMERCE
OFFICE OF THE ADDITIONAL DIRECTOR GENERAL OF FOREIGN TRADE.
NISHTA BHAWAN, 48, VITHALDAS THAKERSEY MARG, NEW MARINE LINES,CHURCHGATE, MUM-20.

=+= FREE SALE AND COMMERCE CERTIFICATE =+=
=====+=====

The **11** Item as per Annexure A(as per list attached) Manufactured by **M/s. PHILIPS INDIA LTD, 7, JUSTICE CHANDRA MADHAB ROAD,KOLKATA,WEST BENGAL, PIN-700020,** holding (IEC **No. 0388013567)** are "freely permitted for sale in India as well as freely exportable".

This Certificate is valid for a period of 2 years from the date of issue.

Encl: Annexure- A **(List of products)** as above.

Place: Mumbai.

Date: 11.06.2019.

NOTARY PUBLIC ASHOK KUMAR ADVOCATE L. No. 44/93 GOVT. OF INDIA

अविल डिमेलो
सहायक महानिदेशक विदेश व्यापार
AVIL DMELLO
ASST. DIRECTOR GENERAL OF FOREIGN TRADE

(Avil Dmello)
ASST. Director General of Foreign Trade
For Additional Director General of Foreign Trade.

NOTE: 1. This certificate is based on declaration by the above firm that items of exports shown in Annexure ARE NEITHER RESTRICTED NOR PROHIBITED FOR EXLPORT.

(Issued from File No. 03/27/108/00107/AM-20)

PHILIPS INDIA LIMITED

C27074

PHD Chamber of Commerce and Industry - 4 SEP 2019 New Delhi-110 001

ATTESTED
Gur Singh Dharwal
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

PHD Chamber of Commerce and Industry
New Delhi-110 001
- 4 SEP 2019

ANNEXURE A

Performa for Submission of list of Products

Sl. No.	Name of Product	ITC (HS) Code	Manufacturers/ Exporters name and address	Is the product licensed under the Drugs & Cosmetics Acts for manufacture and sale.	Description of the product including use (attach literature, if required.)
1	Allura FC	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	AERB Type approval number 99-TA-815	Product Desc: Radiography and Fluroscopy diagnostic and interventional procedures
2	BV Vectra (Mobile C Arm)	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	15-TA-66691	Product Desc: Orthopaedic procedures
3	Allura Centron (Interventional Radiology)	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	16-TA-103828	Product Desc: Radiography, Fluroscopy diagnostic interventional and cardio vascular procedures.
4	Veradius Unity	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	19-TA-369674	Product Desc: Radiography and fluoroscopy procedures.
5	BV Endura	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari	99-TA-438	Product Desc: Radiography and fluoroscopic procedures.

PHILIPS INDIA LIMITED

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सहायक महानिदेशक विदेश व्यापार
AVIL DMELLO
ASST. DIRECTOR GENERAL OF FOREIGN TRADE

PHD Chamber of Commerce and Industry
New Delhi-110 001
- 4 SEP 2009

Sl. No.	Name of Product	ITC (HS) Code	Manufacturers/ Exporters name and address	Is the product licensed under the Drugs & Cosmetics Acts for manufacture and sale.	Description of the product including use (attach literature, if required.)
			District: Pune, Maharashtra 410501, India		
6	BV Pulsera	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	99-TA-440	Product Desc: Radiography and fluoroscopy procedures.
7	Intuis	90221490	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	15-TA-46702	Product Desc: Diagnostic & interventional services, including cardiac, vascular, and EP interventions, as well as biopsy, drainage,& Vertebroplasty procedures.
8	IntelliSpace Breast	8523 80 20	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	NA	Product Desc: workstation software package intended for viewing, manipulation, reporting and communication of digital mammography images as well as other modality images
9	Philips Fetal Doppler	9018 12 90	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	NA	Product Desc: Fetal heart rate monitor with a probe that uses Doppler ultrasound waves to detect the fetal heart.
10	Children's Respiration Monitor	9018 90 19	**Philips India Limited**	NA	Product Desc: The "Children's Respiration Monitor" measures the respiration

PHILIPS INDIA LIMITED

अविल दिल्ली
सहायक महानिदेशक-विदेश व्यापार
AVIL DHELLO
ASST. DIRECTOR GENERAL OF FOREIGN TRADE

Sl. No.	Name of Product	ITC (HS) Code	Manufacturers/ Exporters name and address	Is the product licensed under the Drugs & Cosmetics Acts for manufacture and sale.	Description of the product including use (attach literature, if required.)
			Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India		rate in children under five years old and automatically classify fast breathing rate according to the IMCI guidelines set by the "World Health Organization".
11	Philips e-Alert	9030 8990	**Philips India Limited** Plot no. B-79, MIDC, Phase-II Chakan, Taluka - khed, Village - Savardari District: Pune, Maharashtra 410501, India	NA	Product Desc: e-Alert continuously monitors key parameters of MRI system and issues an automatic alert if something is amiss

ATTESTED
Gur Singh Dhanwal
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

027074

PHD Chamber of Commerce and Industry
New Delhi-110 001
- 4 SEP 2009

अविल डिमेलो
सहायक महानिदेशक विदेश व्यापार
AVIL DMELLO
ASST. DIRECTOR GENERAL OF FOREIGN TRADE

PHILIPS INDIA LIMITED

NOTARY PUBLIC
GOVT. OF INDIA
ASHOK KUMAR
ADVOCATE
L.No. 448

(४)

ATTESTED

NOTARY PUBLIC
DELHI (INDIA)

NOTARY PUBLIC
ASHOK KUMAR
ADVOCATE
L. No. 4448
GOVT. OF INDIA

VALID OUT SIDE INDIA

4 SEP 2019

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

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acting in the capacity of

4. và con dấu của Bộ Ngoại giao Ấn Độ
bears the seal/stamp of

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại Niu Đê-li 6. ngày 09 / 09 / 2019
at

7. cơ quan cấp Đại sứ quán Việt Nam tại Ấn Độ
by

8.Số 4020. 5 / 19-HPH
N°

Ký tên và đóng dấu
Signature and seal/stamp

TL. ĐẠI SỨ / FOR THE AMBASSADOR
Bí thư thứ Hai / Second Secretary

Nguyễn Sỹ Dũng

95981

5 SEP 2019

सं० No. दिनांक Date

वाणिज्य मंडल में सहायक सचिव या संयुक्त/उप सचिव के हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asstt. Secretary/Dy. Secretary/Secretary of Chamber of Commerce Attested.

विदेश मंत्रालय इन दस्तावेज के किसी भी विषय वस्तु की जिम्मेदारी नहीं लेता।
Ministry of External Affairs accepts no responsibility for the contents of this document.

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS GOVT. OF INDIA NEW DELHI

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
कौ. प. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

SINGAPORE ACADEMY OF LAW

AUTHENTICATION CERTIFICATE

I hereby certify that –

S H Almenoar is a duly appointed Notary Public practising in Singapore, and that the signature appearing at the foot of the annexed Notarial Certificate dated 11th July 2019, is the signature of the said S H Almenoar.

This Certificate is not valid if the seal of the Singapore Academy of Law is removed or altered in any way whatsoever. This Certificate does not authenticate or confirm the content of the Document attached to the annexed Notarial Certificate.

SINGAPORE ACADEMY OF LAW CERTIFICATION SEAL

Dated this 12th day of July 2019.

LAI WAI LENG
SENIOR MANAGER
SINGAPORE ACADEMY OF LAW

1907194

Certified true signature

MINISTRY OF FOREIGN AFFAIRS SINGAPORE

17 JUL 2019

MOHAMAD FAZUDDIN

1 Coleman Street, #08-06 The Adelphi, Singapore 179803
Tel: +65 6332 4388 | Fax: +65 6333 9747 | Website: http://www.sal.org.sg

ĐẠI SỨ QUÁN NƯỚC CỘNG HÒA XHCN VIỆT NAM TẠI CH XINH-GA-PO
Embassy of the S.R. of Vietnam in the Republic of Singapore

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

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4. và con dấu của / *bears the seal/stamp of*: BỘ NGOẠI GIAO XINH-GA-PO

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. Tại / *at*: XINH-GA-PO / *Singapore*
6. ngày / *date*: 17 July 2019
7. Cơ quan cấp / *by*: DSQ nước CHXHCN Việt Nam tại CH Xinh-ga-po. / *Embassy of the S.R. of Vietnam in the Republic of Singapore*
8. Số / *N°*: 221/07/2019

Ký tên và đóng dấu
Signature and seal/stamp
Bí thư thứ Hai/Second Secretary

Vũ Thị Hương Trà

NOTARIAL CERTIFICATE

TO ALL TO WHOM THESE PRESENTS SHALL COME

I, S H ALMENOAR, Notary Public, duly authorised admitted and practising in the Republic of Singapore, DO HEREBY CERTIFY that the original of the following document have been shown to me:

Certificate of Free Sale for Medical Device
HSA 600:36/18
Certificate No. FSC/206/2019
Date of Issue: 03 Jul 2019

AND I DO HEREBY FURTHER CERTIFY that I have seen the said original document and the document annexed hereto is a true copy of the said original document.

IN FAITH AND TESTIMONY WHEREOF, I, the said Notary Public have hereunto subscribed my name and affixed my Seal of Office at Singapore this 11th day of July, 2019.

WHICH I ATTEST

NOTARY PUBLIC
SINGAPORE

REPUBLIC OF SINGAPORE
NOTARY PUBLIC

NOTARY PUBLIC
S H Almenoar
N2019/0002
1 Apr 2019 – 31 Mar 2020
SINGAPORE

ĐẠI SỨ QUÁN NƯỚC CỘNG HÒA XHCN VIỆT NAM TẠI CH XINH-GA-PO
Embassy of the S.R. of Vietnam in the Republic of Singapore

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5. Tại / *at*: XINH-GA-PO *Singapore*
6. ngày / *date*: 17 July 2019
7. Cơ quan cấp / *by*: ĐSQ nước CHXHCN Việt Nam tại CH Xinh-ga-po. *Embassy of the S.R. of Vietnam in the Republic of Singapore*
8. Số / *N°*: 221/07/2019

Ký tên và đóng dấu
Signature and seal/stamp
Bí thư thứ Hai/Second Secretary

Vũ Thị Hương Trà

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N2019/0002
1 Apr 2019 – 31 Mar 2020
SINGAPORE

HSA

Health Sciences Authority
Republic of Singapore

HSA 600:36/18
Date of Issue: 03 Jul 2019

Certificate No.
FSC/206/2019

CERTIFICATE OF FREE SALE FOR MEDICAL DEVICE

It is hereby certified that the following medical device products may be supplied in Singapore subject to the device being listed on the Singa

Device Proprietary/Brand Name	:	*Please refe*
Intended Use	:	*Please refe*
Manufacturing Site	:	*PLEXUS C* *2400 MILL* *IL 60009, U*
Product Owner	:	*MEDTRON* *9000 AUTC* *POINTE CI*
Registrant	:	*MEDTRON* *50 PASIR F* *MAPLETRI*

Please refer overleaf for a definition of the terms used in this

2 The information provided in this certificate and information submitted to the Authority.

3 The information provided in this certificate and the date of issuance.

ĐẠI SỨ QUÁN NƯỚC CỘNG HÒA XHCN VIỆT NAM TẠI CH XINH-GA-PO
Embassy of the S.R. of Vietnam in the Republic of Singapore

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Bí thư thứ Hai/Second Secretary

Vũ Thị Hương Trà

DR CHRISTOPHER LAM XU FU
SENIOR REGULATORY SPECIALIST
for GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

HEALTH SCIENCES AUTHORITY HSA SINGAPORE

This certificate shall not be construed as an endorsement of the medical device product by the Health Sciences Authority

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NOTARY PUBLIC
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HSA

Health Sciences Authority
Republic of Singapore

HSA 600:36/18
Date of Issue: 03 Jul 2019

Certificate No.
FSC/206/2019

CERTIFICATE OF FREE SALE FOR MEDICAL DEVICE

It is hereby certified that the following medical device products may be supplied in Singapore subject to the device being listed on the Singapore Medical Device Register.

Device Proprietary/Brand Name	:	*Please refer to attached Schedule.*
Intended Use	:	*Please refer to attached Schedule.*
Manufacturing Site	:	*PLEXUS CORP.* *2400 MILLBROOK DRIVE, BUFFALO GROVE,* *IL 60009, UNITED STATES*
Product Owner	:	*MEDTRONIC CRYOCATH LP* *9000 AUTOROUTE TRANSCANADIENNE,* *POINTE CLAIRE, QUEBEC H9R 5Z8, CANADA*
Registrant		*MEDTRONIC INTERNATIONAL, LTD.* *50 PASIR PANJANG ROAD, #04-51* *MAPLETREE BUSINESS CITY, SINGAPORE 117384*

Please refer overleaf for a definition of the terms used in this certificate.

2 The information provided in this certificate and attached Schedule is based on the information submitted to the Authority.

3 The information provided in this certificate and attached Schedule is accurate as on the date of issuance.

DR CHRISTOPHER LAM XU FU
SENIOR REGULATORY SPECIALIST
for GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

HEALTH SCIENCES AUTHORITY HSA SINGAPORE

This certificate shall not be construed as an endorsement of the medical device product by the Health Sciences Authority

Definition of Terms

Manufacturing Site:
The location where the manufacture of a health product is carried out.
Manufacture, in relation to a health product, means to make, fabricate, produce or process the health product and includes —

(a) any process carried out in the course of so making, fabricating, producing or processing the health product; and
(b) the packaging and labelling of the health product before it is supplied

Product Owner:
in relation to a health product, means a person who –

(a) supplies the health product under his own name, or under any trade-mark, design, trade name or other name or mark owned or controlled by him; and
(b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf

Registrant:
in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the Health Products Act

Supply
in relation to a health product, means to transfer possession of the health product by any means whether or not for reward, and includes the following:

(a) to sell the health product, whether by retail, wholesale or auction;
(b) to expose or display the health product as an invitation to treat;
(c) to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;
(d) to supply the health product in connection with —
    (i) a contract for the provision of any goods or the performance of any service; or
    (ii) any advertising, sponsorship or promotional activity;
(e) to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;
(f) to offer, agree or attempt to supply the health product in any of the ways described in paragraphs (a) to (e) or to cause or permit the health product to be so supplied; and
(g) to keep or possess the health product for the purpose of supplying it in any of the ways described in paragraphs (a) to (f)

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SINGAPORE

Certificate No.
FSC/206/2019

THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use
1	Medtronic CryoConsole System	The CryoConsole, together with its components and specified catheters, is for use in performing cardiac ablation procedures.

END OF PRODUCT LIST

HEALTH SCIENCES AUTHORITY HSA SINGAPORE

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APPENDIX I

1. Medtronic CryoConsole System

S/No.	Model/Description	Product Number
1.	CryoConsole 106A2-K	106A2-K

END OF PRODUCT LIST

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