



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 in vitro diagnostic marketed by Fujirebio Inc., 2-1-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0410 JAPAN is manufactured under our supervision as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan and is allowed to be sold in Japan.

Product: ESPLINE SARS-CoV-2  
Product code: 231906  
Date of Marking Approval: 2020/5/13  
Marketing Approval Number: 30200EZX00026000

Name of Manufacturing Site: Fujirebio Inc. Ube Facility

Address: 203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi 759-0134 JAPAN

Registration Number: 35EZ280004

No. 3013

TOKYO, date OCT. - 5, 2020



河野典厚

KONO Noriatsu

Director, Medical Device Evaluation Division

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare

For legalization by the foreign consul in Japan,  
this is to certify that the Seal affixed to this document  
is genuine.

Tokyo, OCT 19 2020

*tanakatoshio*

Official  
Ministry of Foreign Affairs  
(Consular Service Division)



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

11. Quốc gia: VIỆT NAM  
Country: Viet Nam

Giấy tờ, tài liệu này  
This public document

12. Do ông (bà): **TANAKA TOSHIE** ký  
Has been signed by

13. Với chức danh: **CÔNG CHỨC**  
Acting in the capacity of **OFFICIAL**

14. 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

15. Tại: Tô-ki-ô  
At: Tokyo

6. Ngày: **18/11/2020**  
Date (dd/mm/yyyy)

11. Cơ quan cấp: ĐÀI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN  
By EMBASSY OF THE S.R. OF VIET NAM IN JAPAN

12. Số: **17-03T/HPHLS**  
IP

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



FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)  
**FREE SALE CERTIFICATE**  
In-vitro Diagnostic Medical Devices (IVDs)

N° of Certificate: 000006 02-10-20

Exporting (certifying) country: Belgium

Importing (requesting) country: Vietnam

**SECTION TO BE COMPLETED BY THE APPLICANT OF THE CERTIFICATE**

**1. Name and notification number of IVDs:**

- 1) Lumipulse G SARS-CoV-2 Ag Immunoreaction Cartridges (Ref.260340) - Notification n°: BE-CA01/1-90021-00016-IVD  
2) Lumipulse G SARS-CoV-2 Ag Callibrators set (Ref.231869) - Notification n°: BE-CA01/1-90021-00017-IVD  
3) Lumipulse SARS-CoV-2 Ag Sample Extraction Solution set for Nasopharynx swab (Ref.231883) - Notification n°: BE-CA01/1-90021-00018-IVD  
4) Lumipulse SARS-CoV-2 Ag Controls (Ref.231876) - Notification n°: BE-CA01/1-90021-00019-IVD  
5) ESPLINE SARS-CoV-2 (Ref.231906) - Notification n°: BE-CA01/1-90021-00020-IVD

1.1. Grouping according to Directive 98/79/EC:

- IVD List A annex II  
 IVD List B annex II  
 Device for self-testing not in annex II  
 Other

1.2. Does the product contain radioactive substances?

No

If yes, which radioisotope and how much Becquerel? NA

1.3. Is this product authorized to be placed on the market for use in the exporting country?

Yes

1.4. Is this product actually on the market in the exporting country?

Yes

1.5. Does the exported product carry the CE mark according to Directive 98/79/EC?

Yes

**2. Information regarding the manufacturer:**

2.1. Manufacturer (according to the definition of Directive 98/79/EC): name and address:

Fujirebio Inc. 2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo 163-0410 Japan

2.2. Applicant for certificate:

Fujirebio Europe N.V., Technologiepark 6, 9052 Gent, Belgium

2.3. Name and number of the Notified Body (if applicable): NA


2.4. Has the manufacturer been certified to be in compliance with ISO 9000/ EN 13485 standards? Yes

If yes state the name of the organisation that delivered the certificate: TÜV SÜD Product Service GmbH

If no, please explain: NA

**RESERVED FOR THE ADMINISTRATION**

The IVD as described above is presumed to meet the applicable provisions of Directive 98/79/EC and can be placed on the market in the exporting country.

Address of certifying authority:		FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS EUROSTATION II, Victor Hortaplein 40 bus 40, 1060 BRUSSELS (BELGIUM) Telephone n°: +32 2 528.40.00
Date:	02/10/2020	
Stamp:		
		Name of authorized person: Xavier De Cuyper Chief Executive Officer P.O. Hugues MALONNE Directeur général - DG-POST




B 00283633

**LEGALISATIE - LEGALISATION**

Gezien voor de legalisatie van de handtekening van :  
Vu pour légalisation de la signature de :  
Geschen zur Legalisation der Unterschrift von :  
*Malonne Hugues*

Onder Nr./Sous le n°/Unter Nr. : 201095028005


Tel/In - Bruxelles/Bruxelles/Brüssel Op/Le/An

Stempel/Scéau/Stempel:  Ondertekent

Document/Document/Dokument *Attestatie*

Prijs/Prix/Preis: 2

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Certe légalisation ne garantit pas l'authenticité du contenu  
Diese Legalisation dient nicht dem Beweis des Authentizitäts des  
Dere legalisatie controleren? Verifier cette légalisation? Diese L  
https://legalisatie.diplomatie.be



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

**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION**

1. Quốc gia  
Country **VIỆT NAM  
Vietnam**

Giấy tờ, tài liệu này  
This public document

2. do Ông (Bà) ..... Veldeman Martine ..... ký  
has been signed by

3. với chức danh ..... Viên chức lãnh sự .....  
Acting in the capacity of: **Consular Officer**

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


được chứng nhận/hợp pháp hóa lãnh sự  
Certified

5. tại **Brux-xen** 6. Ngày **14 / 10 / 2020**  
at the

7. Cơ quan cấp ĐSQ CHXHCN VIỆT NAM TẠI BỈ  
by

8. Số 873/2020 - CNLS/HPHLS  
N°

TL. Đại sứ/ For the Ambassador  
Bí thư thứ Ba/Third Secretary

  
Trưởng Ngoại Trang