

Ngày 23 tháng 10 năm 2023

23 Oct 2023

Vui lòng xem danh mục sản phẩm tại trang 6

## GIẤY ỦY QUYỀN

### LETTER OF AUTHORIZATION

Kính gửi/To:

- Bộ Y tế / Ministry of Health
- Các cơ quan hữu quan / Whom it may concern

Chúng tôi, **Fujirebio Inc., 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan**, với tư cách là chủ sở hữu trang thiết bị y tế bằng văn bản này ủy quyền cho Công ty TNHH ARQon Việt Nam, địa chỉ tại Số 23, tổ 10, đường Lĩnh Nam, Phường Lĩnh Nam, Quận Hoàng Mai, Hà Nội, Việt Nam được lưu hành tại thị trường Việt Nam các trang thiết bị y tế sau: xin xem phụ lục được đính kèm.

*We, Fujirebio Inc. having address at 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan, as the owner of the medical devices listed hereunder, hereby authorize ARQon Vietnam Co., Ltd, located at No. 23, group 10, Linh Nam Street, Linh Nam Ward, Hoang Mai District, Hanoi, Vietnam to register/place the following medical devices to the market of Vietnam: please see attached appendix.*

Chúng tôi cam kết cung cấp, hỗ trợ các yêu cầu liên quan đến thông tin, chất lượng và bảo đảm các điều kiện về bảo hành, bảo trì, bảo dưỡng và cung cấp vật tư, phụ kiện thay thế trang thiết bị y tế nêu trên.

*We hereby commit to provide and support any inquiry related to the information and quality of the medical devices, guarantee all warranty, maintenance and service conditions and supply replacement materials and accessories for the medical devices.*

Thư ủy quyền này hiệu lực đến thời điểm: 31/12/2027

*This Letter of Authorization shall be valid until 31 December 2027.*

**Người đại diện hợp pháp của Chủ sở hữu**  
***Legal representative of the Product Owner***

*Hitomi Ishii*

Name: Hitomi Ishii

Designation: Senior Manager,

Regulatory Affairs 1st Section, Fujirebio Inc.

**Phụ lục /Appendix:**  
**Danh mục trang thiết bị y tế /List of medical devices**

S/N.	Product name (simplified)	Product Official Name
1	LUMIPULSE G1200	LUMIPULSE G1200
2	LUMIPULSE G600II	LUMIPULSE G600II
3	Lumipulse G HBsAb-N	Lumipulse G HBsAb-N Immunoreaction Cartridges
		Lumipulse G HBsAb-N Calibrators
4	Lumipulse G HBcAb-N	Lumipulse G HBcAb-N Immunoreaction Cartridges
		Lumipulse G HBcAb-N Calibrators
5	Lumipulse G HBcrAg	Lumipulse G HBcrAg Immunoreaction Cartridges set
6	Lumipulse G HAVAb	Lumipulse G HAVAb Immunoreaction Cartridges
		Lumipulse G HAVAb Calibrators
7	Lumipulse G HAVIgM	Lumipulse G HAVIgM Immunoreaction Cartridges set
8	Lumipulse G HCVAAb	Lumipulse G HCV Ab Immunoreaction Cartridges set
9	Lumipulse G HIVAg/Ab	Lumipulse G HIV Ag/Ab Immunoreaction Cartridges set
10	Lumipulse G HBcIgM	Lumipulse G HBcIgM Immunoreaction Cartridges set
11	Lumipulse G HBeAg	Lumipulse G HBeAg Immunoreaction Cartridges set
12	Lumipulse G HBsAg-Quant	Lumipulse G HBsAg-Quant Immunoreaction Cartridges
		Lumipulse G HBsAg-Quant Calibrators
		Lumipulse G HBsAg-Quant Confirmation
13	Lumipulse G HBsAg	Lumipulse G HBsAg Immunoreaction Cartridges
		Lumipulse G HBsAg Calibrators
14	Lumipulse G HTLV-I/II	Lumipulse G HTLV-I/II Immunoreaction Cartridges set
15	Lumipulse G Free PSA	Lumipulse G Free PSA Immunoreaction Cartridges
		Lumipulse G Free PSA Calibrators
16	Lumipulse G PSA-N	Lumipulse G PSA-N Immunoreaction Cartridges
		Lumipulse G PSA-N Calibrators
17	Lumipulse G TP-N	Lumipulse G TP-N Immunoreaction Cartridges set



18	Lumipulse G TPOAb	Lumipulse G TPOAb Immunoreaction Cartridges set
19	Lumipulse G CEA-N	Lumipulse G CEA-N Immunoreaction Cartridges
		Lumipulse G CEA-N Calibrators
20	Lumipulse G AFP-N	Lumipulse G AFP-N Immunoreaction Cartridges
		Lumipulse G AFP-N Calibrators
21	Lumipulse G Testosterone	Lumipulse G Testosterone Immunoreaction Cartridges
		Lumipulse G Testosterone Calibrators
		Lumipulse G Specimen Diluent 3
22	Lumipulse G FT4-N	Lumipulse G FT4-N Immunoreaction Cartridges
		Lumipulse G FT4-N Calibrators
23	Lumipulse G T3	Lumipulse G T3 Immunoreaction Cartridges
		Lumipulse G T3 Calibrators
		Lumipulse G Specimen Diluent 4
24	Lumipulse G CA19-9-N	Lumipulse G CA19-9-N Immunoreaction Cartridges
		Lumipulse G CA19-9-N Calibrators
25	Lumipulse G Prolactin	Lumipulse G Prolactin Immunoreaction Cartridges
		Lumipulse G Prolactin Calibrators
26	Lumipulse G KL-6	Lumipulse G KL-6 Immunoreaction Cartridges
		Lumipulse G KL-6 Calibrators
27	Lumipulse G FT3-III	Lumipulse G FT3-III Immunoreaction Cartridges
		Lumipulse G FT3-III Calibrators
28	Lumipulse G C-Peptide	Lumipulse G C-Peptide Immunoreaction Cartridges
		Lumipulse G C-Peptide Calibrators
29	Lumipulse G TgAb	Lumipulse G TgAb Immunoreaction Cartridges set
30	Lumipulse G T4	Lumipulse G T4 Immunoreaction Cartridges
		Lumipulse G T4 Calibrators
		Lumipulse G Specimen Diluent 4
31	Lumipulse G PIVKAI-N	Lumipulse G PIVKAI-N Immunoreaction Cartridges
		Lumipulse G PIVKAI-N Calibrators set

32	Lumipulse G TSH-III	Lumipulse G TSH-III Immunoreaction Cartridges
		Lumipulse G TSH-III Calibrators
33	Lumipulse G Insulin-N	Lumipulse G Insulin-N Immunoreaction Cartridges
		Lumipulse G Insulin-N Calibrators
34	Lumipulse G CYFRA	Lumipulse G CYFRA Immunoreaction Cartridges
		Lumipulse G CYFRA Calibrators set
35	Lumipulse G CA125II	Lumipulse G CA125II Immunoreaction Cartridges
		Lumipulse G CA125II Calibrators
36	Lumipulse G $\beta$ HCG	Lumipulse G $\beta$ HCG Immunoreaction Cartridges
		Lumipulse G $\beta$ HCG Calibrators
37	Lumipulse G CA15-3	Lumipulse G CA15-3 Immunoreaction Cartridges
		Lumipulse G CA15-3 Calibrators
38	Lumipulse G IgE	Lumipulse G IgE Immunoreaction Cartridges
		Lumipulse G IgE Calibrators
39	Lumipulse G ProGRP	Lumipulse G ProGRP Immunoreaction Cartridges
		Lumipulse G ProGRP Calibrators set
		Lumipulse G Specimen Diluent 5
40	Lumipulse G FSH-N	Lumipulse G FSH-N Immunoreaction Cartridges
		Lumipulse G FSH-N Calibrators
41	Lumipulse G Progesterone-N	Lumipulse G Progesterone-N Immunoreaction Cartridges
		Lumipulse G Progesterone-N Calibrators
		Lumipulse G Specimen Diluent 6
42	Lumipulse G Ferritin-N	Lumipulse G Ferritin-N Immunoreaction Cartridges
		Lumipulse G Ferritin-N Calibrators
43	Lumipulse G LH	Lumipulse G LH Immunoreaction Cartridges
		Lumipulse G LH Calibrators
44	Lumipulse G BRAHMS PCT	Lumipulse G B•R•A•H•M•S PCT Immunoreaction Cartridges
		Lumipulse G B•R•A•H•M•S PCT Calibrators set



45	Lumipulse G BNP	Lumipulse G BNP Immunoreaction Cartridges
		Lumipulse G BNP Calibrators set
46	Lumipulse G 25-OH Vitamin D	Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges
		Lumipulse G 25-OH Vitamin D Calibrators
47	Lumipulse G E2-III	Lumipulse G E2-III Immunoreaction Cartridges
		Lumipulse G E2-III Calibrators
		Lumipulse G Specimen Diluent 2
48	Lumipulse G whole PTH	Lumipulse G whole PTH Immunoreaction Cartridges
		Lumipulse G whole PTH Calibrators
49	Lumipulse G Myoglobin	Lumipulse G Myoglobin Immunoreaction Cartridges
		Lumipulse G Myoglobin Calibrators
50	Lumipulse G hs Troponin I	Lumipulse G hs Troponin I Immunoreaction Cartridges
		Lumipulse G hs Troponin I Calibrators
51	Lumipulse G CK-MB	Lumipulse G CK-MB Immunoreaction Cartridges
		Lumipulse G CK-MB Calibrators set
52	Lumipulse G HBeAb-N	Lumipulse G HBeAb-N Immunoreaction Cartridges set
53	PIVKA-II and KL-6 Controls	Lumipulse PIVKA-II and KL-6 Controls
54	B•R•A•H•M•S PCT Controls	Lumipulse B•R•A•H•M•S PCT Controls
55	BNP Controls	Lumipulse BNP Controls
56	HBcrAg Controls	Lumipulse HBcrAg Controls
57	HBsAg Controls	Lumipulse HBsAg Controls
58	HCV Controls	Lumipulse HCV Ab Controls
59	HIVAg/Ab Controls	Lumipulse HIV Ag/Ab Controls
60	HTLV-I/II Controls	Lumipulse HTLV-I/II Controls
61	whole PTH Controls	Lumipulse PTH Controls
62	Lumipulse G Specimen Diluent 1	Lumipulse G Specimen Diluent 1
63	Lumipulse G Substrate Solution	Lumipulse G Substrate Solution



64	Lumipulse G Wash Solution	Lumipulse G Wash Solution
65	Lumipulse G SARS-CoV-2 Ag	Lumipulse G SARS-CoV-2 Ag Immunoreaction Cartridges
		Lumipulse G SARS-CoV-2 Ag Calibrators set
66	Sample Extraction Solution set	Sample Extraction Solution set
67	SARS-CoV-2 Ag Controls	Lumipulse SARS-CoV-2 Ag Controls
68	Lumipulse G TSH IFCC	Lumipulse G TSH IFCC Immunoreaction Cartridges
		Lumipulse G TSH IFCC Calibrators
69	Lumipulse G AMH	Lumipulse G AMH Immunoreaction Cartridges
		Lumipulse G AMH Calibrators



令和5年登簿第 435 号

認 証

囑託人 富士レビオ株式会社 薬事統括部薬事1課課長 石井  
ひとみ は、本公証人の前で、別紙編綴の書面に署名した。

よって、これを認証する。

令和5年 10 月 23 日、本公証人役場において

東京都新宿区新宿2丁目9番23号

東京法務局所属

公 証 人  
Notary

青 野 洋 士



AONO Hiroshi

総公証 No 164539 号

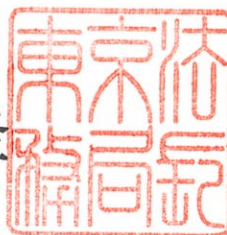
証 明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、  
真実のものであることを証明する。

令和5年 10 月 23 日

東京法務局長

平 光 信 隆



CERTIFICATE

This is to certify that the signature affixed above has been provided by Notary,  
duly authorized by the Tokyo Legal Affairs Bureau and that the Official Seal  
appearing on the same is genuine.

Date OCT. 23. 2023

HIRAMITSU Nobutaka

Director of the Tokyo Legal Affairs Bureau

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

Date OCT. 23. 2023

MAEJIMA Tadashi

Tokyo, \_\_\_\_\_

Official  
Ministry of Foreign Affairs  
(Consular Service Division)





PHÁP



**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): **MAEJIMA TADASHI** 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  
*At: Tokyo*
6. Ngày: **26-10-2023**  
*The (dd/mm/yyyy)*
7. Cơ quan cấp: ĐÀI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN  
*By EMBASSY OF THE S.R. OF VIET NAM IN JAPAN*
8. Số: **MMB01-05J/HPHLS**  
*Nº*

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





Registered No.435

## NOTARIAL CERTIFICATE

This is to certify that Ms. Hitomi Ishii, Senior Manager, Regulatory Affairs 1st Section of Fujirebio Inc., has affixed her signature in my very presence to the attached document.

Dated this 23rd day of October, 2023

AONO Hiroshi

## NOTARY

