

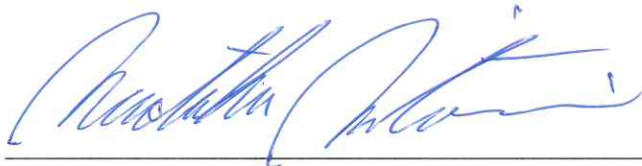
June 14, 2023

To whom it may concern

DECLARATION

We, FUJIFILM Corporation with business address 26-30, Nishiazabu 2-Chome, Minato-ku, Tokyo 106-8620 Japan, here by attest that the attached documents are the true copy taken from the originals.

Sincerely yours,



Naotake Mitsumori

General Manager

Quality Assurance & Regulatory Affairs Div.

Medical Systems Business Division

FUJIFILM Corporation

June 14, 2023

EC CERTIFICATE

umber: 76910CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class IIa, IIb or III)

Manufacturer:

FUJIFILM Corporation

26-30 Nishiazabu
2-Chome Minato-Ku
Tokyo 106-8620
Japan

For the product category(ies)

X-ray films

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

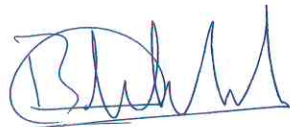
Documents, that form the basis of this certificate:

Certification Notice 76910CN, initially dated 24 December 1997
Addendum, initially dated 15 December 2000

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory. The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 April 2024
Issued for the first time: 24 December 1997
Reissued: 1 April 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 76910CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

X-ray films

Issued to:

FUJIFILM Corporation

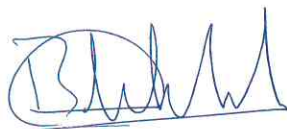
26-30 Nishiazabu
2-Chome Minato-Ku
Tokyo 106-8620
Japan

This certificate covers the following product(s):

X-ray film

Initial date: 15 December 2000
Revision date: 2 October 2006

DEKRA Certification B.V.

A handwritten signature in blue ink, appearing to read "B.T.M. Holtus".

B.T.M. Holtus
Managing Director

A handwritten signature in blue ink, appearing to read "J.A. van Vugt".

J.A. van Vugt
Certification Manager

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令和 5 年登簿第. 289 号
認 証

三森尚武（富士フィルム株式会社メディカルシステム事業部品証薬事部長）の代理人菅康司は、本公証人に対し、三森尚武が添付書面の署名につき、自らしたものであることを承認している旨陳述した。

よって、これを認証する。

令和 5 年 6 月 16 日、本公証人役場において

小田原市栄町1丁目8番1号

横浜地方法務局所属

公 証 人

Notary

佐藤 方生
SATO Masao



証 明

上記署名は、横浜地方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 6 月 16 日

横浜地方法務局長

渡辺英樹



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country : JAPAN
This public document
2. has been signed by **SATO Masao**
3. acting in the capacity of Notary of the Yokohama District Legal Affairs Bureau
4. bears the seal/stamp of **SATO Masao** , Notary

Certified

5. at Tokyo
6. JUN. 16. 2023
7. by the Ministry of Foreign Affairs
8. 23- No 303349
9. Seal/stamp :
10. Signature :



HAMAMOTO Hiroki

For the Minister for Foreign Affairs

Registered No.289 2023

CERTIFICATE OF ACKNOWLEDGEMENT OF NOTARY

On this 16th day of June 2023, SUGA Yasushi personally appeared before me, SATO Masao, a notary in and for the Yokohama Legal Affairs Bureau, with satisfactory evidence of his identification and of his being an agent of MITSUMORI Naotake, and in accordance with the Notary Act of Japan stated that the principal, said MITSUMORI Naotake, had acknowledged affixing his signature to the attached document.

In witness whereof, I set my hand and seal.

Sato Masao



SATO Masao

Notary affiliated with the Yokohama Legal Affairs Bureau
Odawara Notary Office

1-8-1 Sakae - cho, Odawara - shi, Kanagawa - ken, Japan

