FUJIREBIO™ Diagnostics, Inc.

info@fdab.com e-mail
www.fdab.com website
SE556450496601 vat no.
Göteborg place of registered office

Fujirebio Diagnostics AB
Majnabbeterminalen
SE-414 55 Göteborg, Sweden
+46 31 85 70 30 phone
+46 31 85 70 40 fax

CERTIFICATE OF CONFORMITY

We, Fujirebio Diagnostics AB hereby declare that the products listed below comply with the In Vitro Medical Device Directive 98/79/EC and its relevant transposition into the national laws of the member states in which the devices are intended to be placed on the market.

	Prod no	*Prod grouping*
CanAg CA242 EIA	101-10*	Common/Other IVD product
CanAg CA19-9 EIA	120-10*	Common/Other IVD product
CanAg CA15-3 EIA	200-10*	Common/Other IVD product
CanAg PSA EIA	340-10**	Annex II list B
CanAg Free PSA EIA	350-10**	Annex II list B
CanAg CA125 EIA	400-10*	Common/Other IVD product
CanAg CEA EIA	401-10*	Common/Other IVD product
CanAg NSE EIA	420-10*	Common/Other IVD product
CanAg AFP EIA	600-10*	Common/Other IVD product
CanAg S100 EIA	708-10*	Common/Other IVD product
CanAg SCC EIA	800-10*	Common/Other IVD product
CanChek Tumor Marker Control Serum	107-20*	Common/Other IVD product
HE4 EIA	404-10*	Common/Other IVD product
Cyfra 21-1 EIA	211-10*	Common/Other IVD product

Digitally signed by Bolea Petru
Date: 2021.10.22 19:28:45 EEST
Reason: MoldSign Signature
Location: Moldova

* using Annex III as the conformance assessment procedure
** using Annex IV as the conformance assessment procedure.

December 1, 2009 Göteborg

Fujirebio Diagnostics AB

Christina Hall
Managing Director

FUJIREBIO Diagnostics, Inc.

Fujirebio Diagnostics AB
PO Box 121 32
SE-402 42 Göteborg
Sweden

delivery/visiting address
Elof Lindälvs gata 13
SE-414 58 Göteborg
Sweden

vat no.
SE556450496601
place of registered office
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DECLARATION OF CONFORMITY

We, Fujirebio Diagnostics AB hereby declare that the products listed below comply with the In Vitro Medical Device Directive 98/79/EC and its relevant transposition into the national laws of the member states in which the devices are intended to be placed on the market.

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CanAg CA19-9 EIA	120-10*	Common/Other IVD product
CanAg CA242 EIA	101-10*	Common/Other IVD product
CanAg CEA EIA	401-10*	Common/Other IVD product
CanAg Free PSA EIA	350-10**	Annex II list B
CanAg NSE EIA	420-10*	Common/Other IVD product
CanAg ProGRP EIA	220-10*	Common/Other IVD product
CanAg PSA EIA	340-10**	Annex II list B
CanAg S100 EIA	708-10*	Common/Other IVD product
CanAg SCC EIA	800-10*	Common/Other IVD product
CanChek	107-20*	Common/Other IVD product
CYFRA 21-1 EIA	211-10*	Common/Other IVD product
HE4 EIA	404-10*	Common/Other IVD product
Tumor Marker Control	108-20**	Annex II list B
ProGRP Control	230-20*	Common/Other IVD product
Mesothelin Control	360-20*	Common/Other IVD product
Lung Marker Control	240-20*	Common/Other IVD product

* using Annex III as the conformance assessment procedure
** using Annex IV as the conformance assessment procedure.

16 February 2016, Göteborg

Fujirebio Diagnostics AB

Thomas Stjernkvist
QA & RA Manager

TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60139396 0001

Report No.: 21220990 009

Manufacturer:
Fujirebio Diagnostics AB
Elof Lindälvs gata 13
SE-414 58 Göteborg
Sweden

FUJIREBIO

Thomas Stjernkvist, M.Sc.
Regulatory Affairs &
Quality Systems Manager
Fujirebio Diagnostics AB
Elof Lindälvs gata 13
SE-414 58 Göteborg, Sweden
Phone: + 46 (0) 31 304 90 00
www.fdab.com - info@fdab.com

Products: Reagents and reagent products for determining the tumoral marker PSA

Replaces Certificate, Registration No.: HL 60096837 0001

Expiry Date: 2024-05-24

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and verification of manufactured products according to section 6 is required.

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann

Effective Date: 2019-10-16

Date: 2019-07-18

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

Fujirebio Diagnostics AB
Elof Lindälvs gata 13
Box 121 32
SE-414 58 Göteborg
Sweden

To whom it concern

FREE SALES CERTIFICATE

It is hereby certified that Fujirebio Diagnostics AB, Elof Lindälvs gata 13, Box 121 32, SE-414 58 Göteborg, Sweden, is the manufacturer of the product/products listed in the attached product list.

The Swedish Medical Products Agency certifies that these devices are not under restrictions given by the Swedish Medical Product Agency and may be exported without restrictions. The devices are freely marketed in Sweden.

This certificate is valid until May 25, 2022

On behalf of the Swedish Medical Products Agency

Sinikka Gustafsson
Senior Administrative Officer

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Product Name	Article Number
AMH Control	660-20 / 17350066140579
CanAg AFP EIA	600-10 / 17350066140371
CanAg CA125 EIA	400-10 / 17350066140241
CanAg CA15-3 EIA	200-10 / 17350066140081
CanAg CA19-9 EIA	120-10 / 17350066140050
CanAg CA242 EIA	101-10 / 17350066140012
CanAg CEA EIA	401-10 / 17350066140289
CanAg Free PSA EIA	350-10 / 17350066140203
CanAg NSE EIA	420-10 / 17350066140340
CanAg ProGRP EIA	220-10 / 17350066140159
CanAg PSA EIA	340-10 / 17350066140173
CanAg S100 EIA	708-10 / 17350066140388
CanAg SCC EIA	800-10 / 17350066140401
CanChek Tumor Marker Control	107-20 / 17350066140036
CYFRA 21-1 EIA	211-10 / 17350066140135
HE4 EIA	404-10 / 17350066140302
Lung Marker Control	240-20 / 17350066140531
Mesothelin Control	360-20 / 17350066140524
Tumor Marker Control	108-20 / 17350066140043

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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DECLARATION OF CONFORMITY

We, Fujirebio Diagnostics AB hereby declare that the products listed below comply with the In Vitro Medical Device Directive 98/79/EC and its relevant transposition into the national laws of the member states in which the devices are intended to be placed on the market.

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CanAg SCC EIA	800-10*	Common/Other IVD product
CanChek	107-20*	Common/Other IVD product
CYFRA 21-1 EIA	211-10*	Common/Other IVD product
HE4 EIA	404-10*	Common/Other IVD product
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Mesothelin Control	360-20*	Common/Other IVD product
Lung Marker Control	240-20*	Common/Other IVD product

* using Annex III as the conformance assessment procedure
** using Annex IV as the conformance assessment procedure.

22 January 2021, Göteborg

Fujirebio Diagnostics AB

Thomas Stjernkvist
Regulatory affairs and Quality systems Manager

FUJIREBIO

Thomas Stjernkvist, M.Sc.
Regulatory Affairs &
Quality Systems Manager
Fujirebio Diagnostics AB
Elof Lindälvs gata 13
SE-414 58 Göteborg, Sweden
Phone: +46 (0) 31 304 90 00
www.fdab.com - info@fdab.com

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Fujirebio Germany GmbH
Hans-Böckler-Allee 20
30173 Hannover
Germany

has established and applies
a Quality Management System for

Sales, customer services and marketing of
in vitro diagnostics and instruments.

An audit was performed, Order No. **707118450**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-06-19** until **2023-06-18**.

Certificate Registration No.: **12 100 59925 TMS**.

Product Compliance Management
Munich, 2020-05-06

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 57 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

TÜV®

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 083208 0032 Rev. 03

Holder of Certificate: **Fujirebio Inc.**
2-1-1 Nishishinjuku
Shinjuku-ku, Tokyo
163-0410 JAPAN

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control
Design and Development, Production and Distribution of Instruments for Immunoassay, Sampling Tips and Specimen Container
Installation and Servicing of Instruments for Immunoassay

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 083208 0032 Rev. 03

Report No.: **JN1667218**

Valid from: **2021-09-06**
Valid until: **2024-09-05**

Date, **2021-09-02**

Christoph Dicks
Head of Certification/Notified Body

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 083208 0032 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, Production and Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control
Distribution of Instruments for Immunoassay, Sampling Tips and Specimen Container

Fujirebio Inc. Hachioji Facility
51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Design and Development, Production and Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control
Design and Development, Production and Distribution of Instruments for Immunoassay, Sampling Tips and Specimen Container
Installation and Servicing of Instruments for Immunoassay

Fujirebio Inc. Hachioji 2nd Facility
153, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Production and Distribution of Immunoassay Reagent Kits, Substrate Solution, Wash Solution, Specimen Diluent and Control

Fujirebio Inc. Hachioji 3rd Facility
935, Ishikawa-machi, Hachioji-shi, Tokyo, 192-0032 JAPAN

Production and Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control

Fujirebio Inc. Sagamihara Facility
1-3-14, Tanashioda, Chuo-ku, Sagamihara-shi, Kanagawa, 252-0245 JAPAN

Production and Distribution of Immunoassay Reagent Kits, Substrate Solution, Wash Solution, Specimen Diluent and Control

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 083208 0032 Rev. 03

Facility(ies):

Fujirebio Inc. Tokachi Obihiro Facility
8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun, Hokkaido, 080-0341 JAPAN

Production and Distribution of Immunoassay Reagent Kits, Substrate Solution, Wash Solution, Specimen Diluent and Control

Fujirebio Inc. Ube Facility
203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi, 759-0134 JAPAN

Production and Distribution of Immunoassay Reagent Kits, Substrate Solution, Wash Solution, Specimen Diluent and Control

Fujirebio Inc. Distribution Center
1-17-19, Haijima-cho, Akishima-shi, Tokyo, 196-0002 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control
Distribution of Instruments for Immunoassay, Sampling Tips and Specimen Container

Fujirebio Inc. Kuki Distribution Center
1662, Shimohayami, Kuki-shi, Saitama, 346-0022 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control
Distribution of Instruments for Immunoassay, Sampling Tips and Specimen Container

Fujirebio Inc. Asahikawa Facility
23-1975-167, Minamiyonjodori, Asahikawashi, Hokkaido, 078-8334 JAPAN

Production and Distribution of Immunoassay Reagent Kits, Substrate Solution, Wash Solution, Specimen Diluent and Control

-/-

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