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

Digitally signed by Bolea Petru
Date: 2021.06.22 09:36:01 EEST
Reason: MoldSign Signature
Location: Moldova

FUJIREBIO

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Fujirebio Diagnostics AB
Elof Lindälvs gata 13
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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.

Effective Date: 2019-10-16

Date: 2019-07-18

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann

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
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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

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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.

Product name	*Prod No*	*Product grouping*
CanAg AFP EIA	600-10*	Common/Other IVD product
CanAg CA125 EIA	400-10*	Common/Other IVD product
CanAg CA15-3 EIA	200-10*	Common/Other IVD product
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.

22 January 2021, Göteborg

Fujirebio Diagnostics AB

Thomas Stjernkvist
Regulatory affairs and Quality systems Manager

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