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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 083208 0040 Rev. 02

Manufacturer:

Fujirebio Inc.
1-8-1 Akasaka
Minato-ku, Tokyo
107-0052, JAPAN

SRN Manufacturer - JP-MF-000011221

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 083208 0040 Rev. 02

Report No.:	**JN2068411_CN**
Preceding Certificate No.:	**V12 083208 0040 Rev. 01**
Valid from:	**2023-11-21**
Valid until:	**2027-01-24**
Date of Initial Issuance:	**2022-01-25**

Marta Carnielli
Head of Certification IVD

Issue date: 2023-11-21

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	**Class B**
Device Group:	**W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)**
Intended Purpose:	**IVR 0601 - Devices intended to be used for screening/confirmation of specific disorders/impairments**

Classification:	**Class B**
Device Group:	**W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)**
Intended Purpose:	**IVR 0609 - Other devices intended to be used to define or monitor physiological status and therapeutic measures**

Classification:	**Class C**
Device Group:	**W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)**
IVP Code:	**IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays**
Intended Purpose:	**IVR 0506 - Other devices intended to be used to determine markers of infections/immune status**

The validity of this certificate depends on conditions and/or is limited to the following:	**- none -**

Revision History:

Rev.	Dated	Report	Description
00	2022-01-25	JN1700134	-
01	2022-09-07	JN1823741_CN	-
02	2023-11-21	JN2068411_CN	Amended: Change of certificate holder's data

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