Document Information:

Document Author:	Parker, Kati {DQRE~Pleasanton}
Business Area / Unit:	Roche Professional Diagnostics
Confidentiality:	Confidential
Document Class:	Quality System Record
Document Type:	Quality System Record
Document Creator:	Parker, Kati {DQRE~Pleasanton}
Document Lifecycle Status:	Reference
Valid From:	03-Aug-2022 22:52:57 (UTC)
Valid To:	
Document Title:	R_V12_EU QMS Certificate (IVDR)
Document Number:	0000000000001200000589001
Document Version:	03
Template:	No
Global Group:	Regulatory Affairs
Global SubGroup:	Certificate
Language:	English
Site:	RDG Germany
Department:	R_RegAffairs RPD Germany
Document Description:	V12_0102830639 Rev. 02
Description of change:	Application Identification: 425/2021 (Number of Change Decision)

Electronic Signatures:

Signed By:	parkek11 (Kati Parker {DQRE})
Role:	Approver
Signature Differentiation:	Regulatory Affairs
Signed Date:	03-Aug-2022 22:46:11 (UTC)

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 010283 0639 Rev. 02

Manufacturer: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
GERMANY

SRN Manufacturer: DE-MF-000006260

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 010283 0639 Rev. 02

Report No.: 713236941_IVDR / 713236941_CN

Preceding Certificate No.: V12 010283 0639 Rev. 01

Valid from: 2022-08-03

Valid until: 2025-12-14

Date of Initial Issuance: 2020-12-15

Issue date: 2022-08-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

TÜV SÜD 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 010283 0639 Rev. 02

Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0607 - Devices intended to be used for detection of pregnancy or fertility testing

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

TÜV SÜD 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 010283 0639 Rev. 02

Classification:	B
Device Group:	W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	B
Device Group:	W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	B
Device Group:	W0201 - CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

TÜV SÜD 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 010283 0639 Rev. 02

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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 010283 0639 Rev. 02

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0606 - Devices intended to be used for non-infectious disease staging

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	C
Device Group:	W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP Code:	IVP 3005 - In vitro diagnostic devices which require knowledge regarding coagulometry
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

Classification:	C
Device Group:	W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP Code:	IVP 3005 - In vitro diagnostic devices which require knowledge regarding coagulometry
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

TÜV SÜD 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 010283 0639 Rev. 02

Classification:	C
Device Group:	W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP Code:	IVP 3010 - In vitro diagnostic devices which require knowledge regarding microscopy
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	C
Device Group:	W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP Code:	IVP 3010 - In vitro diagnostic devices which require knowledge regarding microscopy
Intended Purpose:	IVR 0302 - Other devices intended to be used for markers of cancer and non-malignant tumours

Classification:	C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0501 - Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents

Classification:	C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	C
Device Group:	W0105 - INFECTIOUS DISEASES
IVP Code:	IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

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 010283 0639 Rev. 02

Classification:	C
Device Group:	W0106 - GENETIC TESTING
IVP Code:	IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	C
Device Group:	W0201 - CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

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

Revision History:

Rev.	Dated	Report
00	2020-12-15	713194890
01	2021-07-27	713209683_IVDR

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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