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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 084062 0012 Rev. 02

Manufacturer:

BÜHLMANN Laboratories AG
Baselstr. 55
4124 Schönenbuch
SWITZERLAND

SRN Manufacturer - CH-MF-000026305

Authorized Representative:

BÜHLMANN Germany GmbH
Marie-Curie-Straße 8, 79539 Lörrach, GERMANY

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 084062 0012 Rev. 02

Report No.:	713269528
Preceding Certificate No.:	V12 084062 0012 Rev. 01
Valid from:	2023-07-03
Valid until:	2027-02-21
Date of Initial Issuance:	2022-02-22

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-07-03

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class 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:	Class 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:	Class 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:	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 B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0603 - Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances

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

Revision History:

Rev.	Dated	Report	Description
00	2022-02-22	713203665_2	-
01	2022-10-18	713253317_CN1	-
02	2023-07-03	713269528	Supplemented: Device(s)/group of device(s) added

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