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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 114429 0002 Rev. 01

Manufacturer:

Generi Biotech s.r.o.
U Fotochemy 1763
Pražské Předměstí
500 02 Hradec Králové
CZECH REPUBLIC

SRN Manufacturer - CZ-MF-000018857

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. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 114429 0002 Rev. 01

Report No.:	713335772_CN
Preceding Certificate No.:	V12 114429 0002 Rev. 00
Valid from:	2024-11-12
Valid until:	2028-10-17
Date of Initial Issuance:	2023-10-18

Marta Carnielli
Head of Certification IVD

Issue date: 2024-11-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. V12 114429 0002 Rev. 01

Classification:	Class 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 0402 - Devices intended to be used to predict genetic disease/disorder risk and prognosis

Classification:	Class 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 0403 - Other devices intended to be used for human genetic testing

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

Version History:

Rev.	Dated	Report	Description
00	2023-10-18	713230259	Initial issuance
01	2024-11-12	713335772_CN	Amended: Change of certificate holder's data

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