



# Certificate

No. Q5 114429 0001 Rev. 00

**Holder of Certificate:** **Generi Biotech s.r.o.**  
Machkova 587/42  
Třebeš  
500 11 Hradec Králové 11  
CZECH REPUBLIC

**Facility(ies):** Generi Biotech s.r.o.  
Machkova 587/42, Třebeš, 500 11 Hradec Králové 11,  
CZECH REPUBLIC

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production of  
In-vitro diagnostic products and reagents  
for human genetic testing**

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 114429 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 114429 0001 Rev. 00)

**Report No.:** 713230259

**Valid from:** 2023-10-18

**Valid until:** 2026-10-17

**Date,** 2023-10-18



Christoph Dicks  
Head of Certification/Notified Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zflg.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. 00**

**Manufacturer:** **Generi Biotech s.r.o.**

Machkova 587/42  
Třebeš  
500 11 Hradec Králové 11  
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. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V12 114429 0002 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12_114429_0002_Rev.00)

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**Issue date:** 2023-10-18

Marta Carnielli  
Head of Certification IVD



## 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. 00**

**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-

### Revision History:

Rev.	Dated	Report	Description
00	2023-10-18	713230259	Initial issuance