



# 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