ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 114429 0001 Rev. 00

Digitally signed by Bolea Petru
Date: 2024.01.22 20:56:09 EET
Reason: MoldSign Signature
Location: Moldova

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:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

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

Report No.: 713230259

Valid from: 2023-10-18
Valid until: 2026-10-17
Date, 2023-10-18

Christoph Dicks
Head of Certification/Notified Body

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