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. 01

Holder of Certificate:

Generi Biotech s.r.o.

U Fotochemy 1763

Pražské Předměstí

500 02 Hradec Králové

CZECH REPUBLIC

Facility(ies):

Generi Biotech s.r.o.
U Fotochemy 1763, Pražské Předměstí, 500 02 Hradec Králové, 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, 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:Q5 114429 0001 Rev. 01

Report No.: 713335772_CN
Valid from: 2024-11-12
Valid until: 2026-10-17
Date, 2024-11-12

Christoph Dicks
Head of Certification/Notified Body

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

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