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

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

Product Service

# Certificate

## No. Q5 103852 0004 Rev. 01

**Holder of Certificate:** **Techno-path Manufacturing Ltd**
Fort Henry Business Park
Ballina Co. Tipperary
IRELAND

**Certification Mark:**


**Scope of Certificate:** **Design, development, manufacture and distribution of in vitro diagnostic reagents for the detection of cardiac markers and control material used in detection of autoimmune status, blood analytes, blood components, blood gases, cancer, cardiac markers, coagulation, disease status, drugs of abuse, endocrine disorders, fertility testing, immune status, pregnancy testing, protein metabolism, sexually transmissible agents, transmissible agents, therapeutic drug monitoring including near patient in-vitro diagnostic medical devices (reagents).**

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 103852 0004 Rev. 01

**Report No.:** 713219707 / 713237092

**Valid from:** 2022-02-13
**Valid until:** 2025-02-12

**Date,** 2022-02-10

Christoph Dicks
Head of Certification/Notified Body


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

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D-ZM-11321-01-00

TÜV SÜD
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**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

**Facility(ies):**

Techno-path Manufacturing Ltd
Fort Henry Business Park, Ballina Co. Tipperary, IRELAND

See Scope of Certificate

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