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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 112744 0001 Rev. 02

Holder of Certificate:

NIHON KOHDEN FIRENZE S.R.L.
Via Torta 72/74
50019 Sesto Fiorentino FI
ITALY

Facility(ies):

NIHON KOHDEN FIRENZE S.R.L.
Via Torta 72/74, 50019 Sesto Fiorentino FI, ITALY

See scope of certificate

Certification Mark:

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

Scope of Certificate:

Manufacturing, and sales of in vitro diagnostic reagents for (automated) haematology analyzer.
Provision of packaging and distribution services of in vitro diagnostic controls and calibrators for hematology.

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 (excluding subclause 7.3), 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:Q6 112744 0001 Rev. 02

Report No.: ITA200220005225

Valid from: 2025-03-29
Valid until: 2028-03-28

Date, 2024-12-16

Christoph Dicks
Head of Certification/Notified Body

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