

CERTIFICATE

Number: 2226120

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Eurotrol B.V.

Keplerlaan 20
6716 BS Ede
The Netherlands

Manufacturer Facility Identifier F003198

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 665/2022, 551/2021, and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

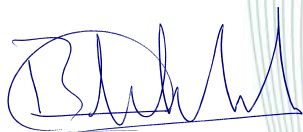
Scope:

The design, development, production and distribution of in-vitro diagnostic reagents used as reference materials for the (bio) chemical measurement of hematology and clinical chemistry and blood gas analytes including point of care in-vitro diagnostic devices

Certificate expiry date: 1 September 2025
Certificate effective date: 1 September 2022
Certified since: 20 September 2019

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



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ADDENDUM

To certificate: 2226120

The management system of the organization(s) and/or location(s) of:

Eurotrol B.V.

Keplerlaan 20
6716 BS Ede
The Netherlands

Certified organization(s) and/or locations:

Different scope

Eurotrol B.V.
Copernicuslaan 33
6716 BM Ede
The Netherlands

Warehousing

Addendum expiry date: 1 September 2025
Addendum effective date: 1 September 2022