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:	2028-09-01
Certificate effective date:	2025-09-01
Certified since:	2019-09-20

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.M. McKenzie
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https://www.dekra-checkme.com/org

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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: 2028-09-01
Addendum effective date: 2025-09-01