

# CERTIFICATE

Number: 2226120

The management system of:

## Eurotrol B.V.

Keplerlaan 20  
6716 BS Ede  
The Netherlands

Manufacturer DUNS 412925992

Conforms with the following standard and regulatory requirements:

# ISO 13485:2016

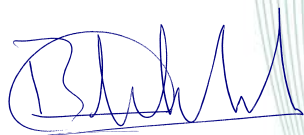
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure  
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009  
Canada: Medical Devices Regulations - Part 1- SOR 98/282  
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act  
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design, development, production, distribution of reference materials for medical (bio) chemical analysis

Certificate expiry date: 2022-09-01  
Certificate effective date: 2019-09-20  
Certified since: 2019-09-20

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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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.

