

# CERTIFICATE

Number: 3822623

The management system of:

## LGC Clinical Diagnostics, Inc.

221 US Route 1  
Cumberland Foreside, ME 04110-1345  
United States Of America

including the implementation meets the requirements of the standard:

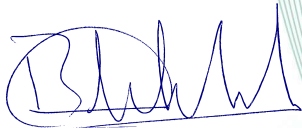
## ISO 13485:2016

### Scope:

The design, development, manufacture and distribution of in-vitro diagnostic calibration verification/linearity test kits for human diagnostic analyzers which are used for management and diagnosis of blood, urine or other body fluid analytes in chemistry, immunoassay, immunology, toxicology, cancer, therapeutic drug, cardiac marker, fertility, endocrine disorder, protein metabolism and coagulation monitoring on in vitro diagnostic manual, semi-automated and automated devices.

Certificate expiry date: 02 October 2024  
Certificate effective date: 10 December 2021  
Certified since: 02 October 2003

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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