

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:

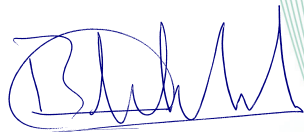
EN ISO 13485:2016

Scope:

The design, development, manufacture and distribution of in-vitro diagnostic calibration verification/linearity test kits and unassayed controls 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, serology and coagulation monitoring on in vitro diagnostic manual, semi-automated and automated devices.

Certificate expiry date: 02 October 2024
Certificate effective date: 20 November 2023
Certified since: 02 October 2003

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

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