

CERTIFICATE

Number: 3822623

The management system of:

Maine Standards Company LLC

221 US Route 1
Cumberland Foreside, ME 04110
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 kits, calibration reagents and quality control products 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: 2 October 2021
Certificate effective date: 16 January 2019
Certified since: 2 October 2003

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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