



Product Service

# Certificate

No. Q5 020747 0242 Rev. 00

**Holder of Certificate:** **Nova Biomedical Corporation**  
200 Prospect Street  
Waltham MA 02454  
USA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices; and Distribution of Lancets

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00)

**Report No.:** 72166286

**Valid from:** 2021-10-29  
**Valid until:** 2024-10-28

**Date,** 2021-10-29

Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Nova Biomedical Corporation  
165 Lexington Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Meters  
for the Management of Diabetes Blood Glucose, Ketone,  
Cholesterol and Uric Acid.

Nova Biomedical Corporation  
39 Manning Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Test  
Strips for the Management of Diabetes Blood Glucose, Ketone,  
Cholesterol and Uric Acid.

Distribution of Near Patient / Point of Care, and Self-Testing Test  
Strips, Meters and Controls. Distribution of Lancets.

Nova Biomedical Corporation  
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation,  
Servicing and Technical Support of In-Vitro Diagnostic Clinical  
Chemistry and Hematology (Co-Oximeter) Medical Devices  
including Near Patient / Point of Care Analyzers, Calibrators,  
Controls, Reagents, Sensors, Kits used in the Detection of Blood  
Analytes, Electrolytes, pH, Metabolites; Self Testing and Near  
Patient / Point of Care In-Vitro Diagnostic Devices for the  
Management of Diabetes Blood Glucose, Ketone, Cholesterol and  
Uric Acid, including Meters, Test Strips and Controls; Self Testing  
In-Vitro Diagnostic Medical Devices for the Determination of the  
percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density  
Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood,  
and Albumin and Creatinine in Urine including Analyzers, Test  
Cartridges and Controls; Contract Manufacturing of Electronic  
Medical Devices; Contract Manufacturing of Disposable Medical  
Devices