



Product Service

# Certificate

No. Q5 020747 0242 Rev. 02

**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 Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; The provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology, In-Vitro Diagnostic General Use Consumables; 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, Certification, Validation and Verification Regulations 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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_020747_0242_Rev.02)

**Report No.:** 72198686

**Valid from:** 2024-10-25

**Valid until:** 2027-10-24 **Thời hạn của ISO 13485**

**Date,** 2024-10-04

Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Nova Biomedical Corporation**  
200 Prospect Street, Waltham MA 02454, USA

Tên, Địa chỉ  
Cơ sở sản xuất

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; the provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology and In-Vitro Diagnostic General Use Consumables.

### **Nova Biomedical Corporation**

39 Manning Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care test strips.

### **Nova Biomedical Corporation**

165 Lexington Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care Instruments

### **Nova Biomedical Corporation**

4 Enterprise Road, Billerica MA 01821, USA

Production of In-Vitro Diagnostic Instruments including Near Patient / Point of Care; Distribution of Finished Goods; Distribution of Lancets.