

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
247561-2017-AQ-RGC-NA-PS

Initial certification date:  
20 January 2006

Valid:  
21 January 2024 – 20 January 2027

This is to certify that the management system of  
**Thermo Fisher Scientific (Shanghai) Instruments  
Co., Ltd.**

T71-6, No. 211, Qin Qiao Road, China (Shanghai) Free Trade Zone, 201206 China  
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**Design & Development, Manufacture, Sales, Distribution and Service of Medical Devices  
Including Tissue Process Equipment for Immunoassay Equipment, Automatic Nucleic Acid  
Extraction Instrument, Auxiliary Equipment including Microplate Washer for Clinical  
Inspection Usage**

Place and date:  
Høvik, 03 January 2024



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 1, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

## Appendix to Certificate

### Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.	Building 3, No.27, Xin Jinqiao Road, Pudong, Shanghai, China 201206	Design & Development of Tissue Process Equipment for Immunoassay Equipment
Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.	T71-6, No. 211, Qin Qiao Road, China (Shanghai) Free Trade Zone, 201206 China	Design & Development of Automatic Nucleic Acid Extraction Instrument, Auxiliary Equipment including Microplate Washer for Clinical Inspection Usage; Manufacture, Sales, Distribution and Service of Medical Devices Including Tissue Process Equipment for Immunoassay Equipment, Automatic Nucleic Acid Extraction Instrument, Auxiliary Equipment including Microplate Washer for Clinical Inspection Usage

