

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 247561-2017-AQ-RGC-NA-PS Rev. 5.0 Project No.: PRJC-36362-2007-MS-C-RGC Initial Certification Date: 20 January 2006 Valid Until: 20 January 2024

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, China
(Unicode : 91310115753186196J)

With sites as listed overleaf.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

**DESIGN & DEVELOPMENT, MANUFACTURE, SALES,
DISTRIBUTION AND SERVICE OF MEDICAL DEVICES
INCLUDING TISSUE PROCESS EQUIPMENT FOR
PATHOLOGICAL ANALYSIS, IMMUNOASSAY EQUIPMENT,
AUXILIARY EQUIPMENT INCLUDING MICROPLATE WASHER
FOR CLINICAL INSPECTION USAGE.**

Place and date:
Høvik, 30 December 2020

For:
DNV GL PRESAFE AS



Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Certificate No.: 247561-2017-AQ-RGC-NA-PS Rev. 5.0 Project No.: PRJC-36362-2007-MS-C-RGC Initial Certification Date: 20 January 2006 Valid Until: 20 January 2024

Site Name	Address	Site Scope
Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.	T71-6, No. 211, Qin Qiao Road, China (Shanghai) Free Trade Zone, China	Design & Development of Auxiliary Equipment including Microplate Washer for Clinical Inspection Usage; Manufacture, Sales, Distribution and Service of Medical Devices Including Tissue Process Equipment for Pathological Analysis, Immunoassay Equipment, Auxiliary Equipment including Microplate Washer for Clinical Inspection Usage
Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.	Building 3, No. 27, Xin Jinqiao Road, Pudong, Shanghai, China	Design & Development of Tissue Process Equipment for Pathological Analysis, Immunoassay Equipment
Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.	U8 WH, GLP, NO. 229, Dongsheng Road, Pudong, Shang-hai, China	Warehouse and IQC

End of Certificate

