

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that: **BioTek Instruments, Inc 100 Tigan Street**

Highland Park PO Box 998 Winooski, VT 05404-0998 USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture, Distribution, Service and Installation of In-Vitro Diagnostic Microplate Readers, Automated Microscopes, Washers, Dispensers, Stackers, Incubators, Pipetting Work Stations and Accessories.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.2126)

Approved by: Geraldine Larkin Chief Executive Officer

Approved by: Caroline Dore Geraghty

Director of Medical Devices
/ Head of Notified Body

Registration Number: MD19.2126 Certification Granted: August 14, 1996

Effective Date: March 13, 2019 Expiry Date: July 12, 2021





Annex to Certificate Number: MD19.2126

Scope of Registration:

The Design, Manufacture, Distribution, Service and Installation of In-Vitro Diagnostic Microplate Readers, Automated Microscopes, Washers, Dispensers, Stackers, Incubators, Pipetting Work Stations and Accessories.

Activity

Headquarters, Design, Manufacturing, Warehouse, Distribution, Service/Repair and Installation

Administration, Distribution, Warehouse, Service/Repair and Installation

Location

BioTek Instruments, Inc 100 Tigan Street Highland Park Winooski, VT 05404-0998 USA File No: MD19.2126

BioTek Instruments GmbH Kocherwaldstrasse 34 D-74177 Bad Friedrichshall Germany File No: MD19.2126/A

Verified by: Operations Manager