

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Tecan Austria GmbH  
Untersbergstraße 1a  
5082 Grödig  
Austria

Facility ID Number: F003857

Holds Certificate No:

**MDSAP 711936**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, distribution and servicing of analyzers and associated accessories for in-vitro diagnostic use.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-06-04

Effective Date: 2023-06-04

Expiry Date: 2026-06-03



BSI Group America Inc. is an MDSAP recognised auditing organization

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