

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Tecan Schweiz AG  
Seestraße 103  
8708 Männedorf  
Switzerland

Facility ID Number: F002717

Holds Certificate No: **MDSAP 705120**

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

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**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, development and manufacture of robotic sample processors and automated solutions for in-vitro diagnostics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-06-19

Effective Date: 2023-07-06

Expiry Date: 2025-06-18



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 705120**

Location	Registered Activities
Tecan Schweiz AG Seestraße 103 8708 Männedorf Switzerland Facility ID Number: F002717	The design, development and manufacture of robotic sample processors and automated solutions for in-vitro diagnostics.
Tecan Schweiz AG Emil Staub Str. 1 8708 Männedorf Switzerland Facility ID Number: F002717	The design, development and manufacture of robotic sample processors and automated solutions for in-vitro diagnostics.
Tecan Schweiz AG Gewerbstrasse 8 8606 Nänikon Switzerland Facility ID Number: F002717	Incoming inspection and warehousing of components and sub assemblies for robotic sample processors and automated solutions for in-vitro diagnostics.



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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.