By Royal Charter

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 Global Regulatory & Quality

Original Registration Date: 2019-06-19 Effective Date: 2025-06-19 Expiry Date: 2028-06-18

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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 Gewerbestrasse 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.

Original Registration Date: 2019-06-19 Effective Date: 2025-06-19 Expiry Date: 2028-06-18