EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Tecan Schweiz AG, Seestrasse 103, CH-8708 Männedorf

for the product:

Freedom EVO 75

Part No.	Model
30025019	**FREEDOM EVO 75**
30025869	**FREEDOM EVO 75**

Software:	**Freedom EVOware® Standard**	**(for 30025019)**
	Freedom EVOware® Plus	**(for 30025869**)

Options:	**Liquid Handling Arm™**
	Robotic Manipulator Arm™

is in conformity with the provisions of the following European Directive(s) when installed in accordance with the installation instructions contained in the product documentation:

Directive 2006/42/EC
on machinery

Directive 2014/30/EU
relating to electromagnetic compatibility

Directive 2011/65/EU
on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2) including Commission Delegated Directive (EU) 2015/863 (RoHS3) amending Annex II to Directive 2011/65/EU

and that the standards referenced below were taken in consideration:

EN 61010-1:2010+A1:2019
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

EN 61010-2-010:2020
Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material

EN 61010-2-081:2020
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

EN 61326-1:2021
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General Requirements

EN 62304: 2006+A1:2015
Medical Device software – Software life cycle processes

EN 62366-1: 2015
Medical Device software – Application of usability engineering to medical devices

EN ISO 15223-1: 2021
Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

EN ISO 14971: 2012
Medical devices – Application of risk management to medical devices

EN ISO 12100: 2010
Safety of machinery - General principles for design - Risk assessment and risk reduction

EN IEC 63000: 2018
Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Tecan Schweiz AG maintains a quality system certified to the following standards:

EN ISO 9001: 2015
Quality management systems – Requirements

EN ISO 13485: 2016
Medical devices – quality Management Systems – Requirements for regulatory purposes

Tecan Schweiz AG, Seestrasse 103, CH-8708 Männedorf 2025-02-17

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Signer Name: Johann Israel
Signing Reason: I approve this document
Signing Time: 2025-02-17 | 6:22:57 PM CET
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Jillian Walker
Signer Name: Jillian Walker
Signing Reason: I approve this document
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Johann Israel
Director QA DACH

Jillian Walker
Associate Director RA Instrumentation

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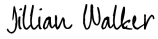
Jillian Walker Jillian.walker@tecan.com Associate Director Regulatory Affairs Instrumentation Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 9CBF24AB-C93B-424D-81F6-BBF9FE61FE0B Using IP Address: 91.212.29.29 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 2/17/2025 5:58:13 PM Viewed: 2/18/2025 8:30:20 AM Signed: 2/18/2025 8:30:45 AM
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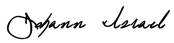
Johann Israel Johann.Israel@tecan.com Director QA Tecan. Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 1B7C02D2-F58F-42FD-8922-6D4DA71CF4B3 Using IP Address: 89.26.17.169 Signed using mobile With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 2/17/2025 5:58:13 PM Viewed: 2/17/2025 6:22:35 PM Signed: 2/17/2025 6:23:04 PM
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