

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®

Part No.	Model	Configuration
10641100	FREEDOM EVO-2 100 BASE	1 LiHA
30020010	FREEDOM EVO-2 100 BASE	MCA 96
30032010	FREEDOM EVO-2 100 BASE	MCA 384
10641150	FREEDOM EVO-2 150 BASE	1 LiHA
10641152	FREEDOM EVO-2 150 BASE	2 LiHA
30020015	FREEDOM EVO-2 150 BASE	MCA 96
30032015	FREEDOM EVO-2 150 BASE	MCA 384
10641200	FREEDOM EVO-2 200 BASE	1 LiHA
10641202	FREEDOM EVO-2 200 BASE	2 LiHA
30020020	FREEDOM EVO-2 200 BASE	MCA 96
30032020	FREEDOM EVO-2 200 BASE	MCA 384

Software: **Freedom EVOware® Standard**
Freedom EVOware® Plus

Options: **Liquid Handling Arm™**
Air LiHa™
Robotic Manipulator Arm™
Robotic Manipulator Arm™ (Long-Z)
Pick and Place Arm™
MultiChannel Arm™ 96
MultiChannel Arm™ 384

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 2014/30/EU

relating to electromagnetic compatibility

Directive 2006/42/EC

on machinery

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 60825-1: 2014

Safety of laser products – Part 1: Equipment classification and 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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Johann Israel
 Director QA DACH

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 Signing Reason: I approve this document
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Jillian Walker
 Associate Director RA Instrumentation

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