

**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 products:

**Freedom EVOLyzer®**

Part No.	Model
<b>30203092</b>	<b>Freedom EVOLyzer-3 100/2</b>
<b>30203093</b>	<b>Freedom EVOLyzer-3 100/4</b>
<b>30203094</b>	<b>Freedom EVOLyzer-3 150</b>
<b>30203095</b>	<b>Freedom EVOLyzer-3 200</b>

Software: Freedom EVOLution

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 61010-2-051: 2015**

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2- 051: Particular requirements for laboratory equipment for mixing and stirring

**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 IEC 61326-1: 2021**

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

**EN 60825-1: 2014+A11:2021**

Safety of laser products – Part 1: Equipment classification and requirements

**EN 62304: 2006+A1:2015**

Medical Device software – Software life cycle processes

**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**

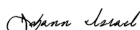
Quality management systems – Requirements

**EN ISO 13485: 2016**

Medical devices – quality Management Systems – Requirements for regulatory purposes

Tecan Schweiz AG, Seestrasse 103, CH-8708 Männedorf, 2022-08-26

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Johann Israel  
Director QARA

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Jillian Walker  
Associate Director  
Regulatory Affairs Instrumentation


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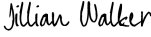
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