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
30203092	**Freedom EVOlyzer-3 100/2**
30203093	**Freedom EVOlyzer-3 100/4**
30203094	**Freedom EVOlyzer-3 150**
30203095	**Freedom EVOlyzer-3 200**

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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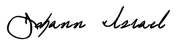
Johann Israel Johann.Israel@tecan.com Director QARA Tecan Switzerland Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 1B7C02D2-F58F-42FD-8922-6D4DA71CF4B3 Using IP Address: 62.202.180.83 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2022-08-26 | 12:43 Viewed: 2022-08-26 | 13:55 Signed: 2022-08-26 | 13:56
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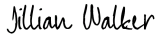
Jillian Walker Jillian.walker@tecan.com Associate Director Regulatory Affairs Instrumentation Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 9CBF24AB-C93B-424D-81F6-BBF9FE61FE0B Using IP Address: 195.141.78.226 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2022-08-26 | 13:56 Viewed: 2022-08-26 | 13:57 Signed: 2022-08-26 | 13:57
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