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:

Fluent®

Part No.	Model
30042011	**INSTRUMENT FLUENT 480 BASE UNIT**
30042021	**INSTRUMENT FLUENT 780 BASE UNIT**
30042031	**INSTRUMENT FLUENT 1080 BASE UNIT**

Software: **FluentControl™**

Options:
Robotic Gripper Arm™ (RGA)
Robotic Gripper Arm™ Long Z (RGA-Z)
Multiple Channel Arm™ 384/96 (MCA384)
Multiple Channel Arm™ (MCA) 96 with optional Gripper
Flexible Channel Arm™ (FCA)
Air Flexible Channel Arm™ (Air FCA)
Air Flexible Channel Arm™ (Air FCA) Multisense
Fluent ID™
Fluent Stacker™ with/ without Barcode reader
Fluent Carousel™
Monitored Incubator Option™(MIO-2)
Te-Shake™
Te-VacS™
Tube Rotator™
Frida Reader™
Resolvex® i300

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 IEC 61010-2-051: 2021+A11:2021
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 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 62366-1: 2015+A1:2020
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 18113-1: 2011
In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

EN ISO 18113-3: 2011
In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 3: In vitro diagnostic instruments for professional use

EN ISO 14971: 2019+A11:2021
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 2024-08-12

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Johann Israel
Signer Name: Johann Israel
Signing Reason: I approve this document
Signing Time: 2024-08-12 | 1:25:56 PM CEST
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Signed by:
Jillian Walker
Signer Name: Jillian Walker
Signing Reason: I approve this document
Signing Time: 2024-08-12 | 1:31:06 PM CEST
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Johann Israel
Director QA

Jillian Walker
Associate Director RA Instrumentation

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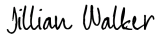
Jillian Walker Jillian.walker@tecan.com Associate Director Regulatory Affairs Instrumentation Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 9CBF24AB-C93B-424D-81F6-BBF9FE61FE0B Using IP Address: 62.2.160.130 Signed using mobile With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2024-08-12 | 13:23 Viewed: 2024-08-12 | 13:30 Signed: 2024-08-12 | 13:31
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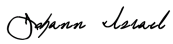
Johann Israel Johann.Israel@tecan.com Director QA Tecan. Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 1B7C02D2-F58F-42FD-8922-6D4DA71CF4B3 Using IP Address: 62.2.160.130 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2024-08-12 | 13:23 Viewed: 2024-08-12 | 13:25 Signed: 2024-08-12 | 13:26
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