UK 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 UK Regulations when installed in accordance with the installation instructions contained in the product documentation:

Electromagnetic Compatibility Regulations 2016
The Supply of Machinery (Safety) Regulations 2008
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

and that the standards referenced below were taken in consideration:

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

BS 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

BS 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

BS 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

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

BS EN 60825-1: 2014+A11:2021
Safety of laser products – Part 1: Equipment classification and requirements

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

BS EN 62366-1: 2015+A1:2020
Medical Device software – Application of usability engineering to medical devices

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

BS EN ISO 18113-1: 2011
In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

BS 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

BS EN ISO 14971: 2019 + A11:2021
Medical devices – Application of risk management to medical devices

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

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

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

BS EN ISO 9001: 2015
Quality management systems – Requirements

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

Person authorized to compile the technical file: Tecan UK Ltd, Theale Court, 11 – 13 High Street, Theale, Reading, RG7 5AH, United Kingdom

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 | 1:26:39 PM CEST
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Johann Israel
Director QA

Signed by:
Jillian Walker
Signer Name: Jillian Walker
Signing Reason: I approve this document
Signing Time: 2024-08-12 | 1:32:44 PM CEST
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Jillian Walker
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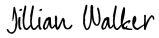
Jillian Walker Jillian.walker@tecan.com Associate Director Regulatory Affairs Instrumentation Tecan Schweiz AG Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 9CBF24AB-C93B-424D-81F6-BBF9FE61FE0B Using IP Address: 62.2.160.130 Signed using mobile With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2024-08-12 | 13:25 Viewed: 2024-08-12 | 13:31 Signed: 2024-08-12 | 13:32
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