

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:

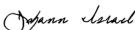
EN ISO 9001: 2015

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

Signed by:

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

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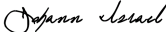
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