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, Switzerland

And

European Authorized Representative
Tecan Austria GmbH Untersbergstr. 1a, 5082 Grödig, Austria
SRN: AT-AR-000044488

for the product

Fluent® Dx

Part No.	Model
30042094	INSTRUMENT FLUENT DX 480 BASE UNIT
30042095	INSTRUMENT FLUENT DX 780 BASE UNIT
30042096	INSTRUMENT FLUENT DX 1080 BASE UNIT
Software:	**FluentControl™ v3.7 with Fluent Dx license**
Options:	**Robotic Gripper Arm™ (RGA)** **Robotic Gripper Arm™ Long Z (RGA-Z)** **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™** **Frida Reader™** **Tube Rotator™** **Resolvex® i300**

GMDN: 65174 – Pipetting system IVD
EMDN code: W02079099 – VARIOUS GENERAL PURPOSE IVD INSTRUMENTS – OTHERS
Basic UDI-DI: 764013748IVS10080001AEF

For products placed on the United Kingdom market the UK responsible person is:
Tecan UK Limited
Theale Court, 11-13 High Street, Theale Reading, Berkshire, RG7 5AH, United Kingdom

Intended purpose:
Fluent Dx is an automated laboratory liquid handling platform for in vitro diagnostic use. The product is intended for the automation of clinical sample preparation and processing of clinical diagnostic assays using human specimens. The type of specimen and specific diagnostic protocol is defined and validated by the user for their selected clinical assay. The product is intended for professional laboratory use by trained personnel. The product is not intended for self-testing or near patient testing.

is in conformity with the provisions of the following European Regulations and Directive(s) when installed in accordance with the installation instructions contained in the product documentation:

Regulation 2017/746 – IVD-R on in vitro diagnostic devices
Classification: Class A according to Rule 5 (b)
Conformity assessment procedure: self-declaration according to Article 17 (Annex II and III)

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
Particular requirements for laboratory equipment for mixing and stirring

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

EC 61010-2-101:2022+A11:2022
Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

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

EN IEC 61326-2-6:2021
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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 18113-1:2022
In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

EN ISO 18113-3:2022
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 81001-5-1:2022
Health software and health IT systems safety, effectiveness and security – Part 5-1: Security Activities in the product life cycle

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

Tecan Switzerland 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, Switzerland

Reviewed by

Signed by:
Johann Israel
Signer Name: Johann Israel
Signing Reason: I have reviewed this document
Signing Time: 2024-12-20 | 8:31:21 AM CET
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Johann Israel
Director QA

And the person Responsible for Regulatory Compliance:

Signed by:
Jillian Walker
Signer Name: Jillian Walker
Signing Reason: I approve this document
Signing Time: 2024-12-20 | 8:45:11 AM CET
9CBF24ABC93B424D81F6BBF9FE61FE0B

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Jillian Walker
Associate Director RA Instrumentation

Below a translation table for this Declaration of Conformity to fulfil IVDR requirement Article 17.1. The table translates to languages required by the Member States in which the device is made available. Other languages will be made available upon request.

English	French	German	Italian	Portuguese	Spanish
EU DECLARATION OF CONFORMITY	DÉCLARATION DE CONFORMITÉ UE	EU-Konformitätserklärung	DICHIARAZIONE DI CONFORMITÀ UE	DECLARAÇÃO UE DE CONFORMIDADE	DECLARACIÓN DE CONFORMIDAD DE LA UE
This declaration of conformity is issued under the sole responsibility of the manufacturer:	Cette déclaration de conformité est délivrée sous la seule responsabilité du fabricant:	Diese EU-Konformitätserklärung wurde unter der Verantwortlichkeit des Herstellers ausgestellt.	La presente dichiarazione di conformità è rilasciata sotto la sola responsabilità del produttore:	Esta declaração de conformidade é emitida sob a exclusiva responsabilidade do fabricante:	Esta declaración de conformidad se emite bajo la exclusiva responsabilidad del fabricante:
SRN	Numéro d'enregistrement unique	Einmalige Registrierungsnummer (SRN - Single Registration Number)	Numero di registrazione unico del fabbricante	Número Único de Registro:	Número de registro único del fabricante
and / or	et / ou	und / oder	e / o	e / ou	y / o
for the product:	pour le produit:	für das Produkt	per il prodotto	para o produto	para el producto
Part No.(or Cat. No.)	Référence (ou Cat. No.)	Artikel Nr. (oder Kat. Nr.)	N. parte (o N. cat.)	Código do produto (ou N° Cat.)	Número de parte (o número de catálogo)
Model	Modèle	Modell	Modello	Modelo	Modelo
Software	Logiciel	Software	Software	Software	Software
Options	Les options	Optionen	Opzioni	Opções	Opciones
GMDN or EMDN:	GMDN ou EMDN:	GMDN oder EMDN:	GMDN o EMDN:	GMDN ou EMDN:	GMDN o EMDN:
Basic UDI-DI:	IUD-ID de base	Basis-UDI-DI:	UDI-DI di base	UDI-DI básico:	UDI-DI básico
Intended purpose:	Objectif prévu:	Zweckbestimmung	Scopo previsto:	Finalidade:	Finalidad prevista:
is in conformity with the provisions of the following European Directive(s)/ <Regulation> <when installed in accordance with the installation instructions contained in the product documentation>	est conforme aux dispositions de la (des) directive(s) européenne(s) suivante(s) / <réglementation> <lorsqu'il est installé conformément aux instructions d'installation contenues dans la documentation du produit>	entspricht den Bestimmungen der folgenden europäischen Richtlinie(n) / <Regulierung> bei Installation gemäß den in der Produktdokumentation enthaltenen Installationsanweisungen>	è conforme alle disposizioni della seguente Direttiva / e Europea / i / <Regolazione> <se installato in conformità con le istruzioni di installazione contenute nella documentazione del prodotto>	está em conformidade com o disposto na (s) seguinte (s) Diretiva (s) Europeia (s) / <Regulamento (s)> <quando instalado de acordo com as instruções de instalação contidas na documentação do produto>	cumple con las disposiciones de la (s) siguiente (s) Directiva (s) / <Regulación (es)> europeas <cuando se instala de acuerdo con las instrucciones de instalación indicadas en la documentación del producto>>

English	French	German	Italian	Portuguese	Spanish
and that the standards referenced below were taken in consideration:	et que les normes référencées ci-dessous ont été prises en considération	und dass die unten genannten Standards berücksichtigt wurden:	e che sono state prese in considerazione le norme sotto riportate:	e que os padrões mencionados abaixo foram levados em consideração:	y que las normas a las que se hace referencia a continuación se tomaron en consideración:
Tecan <add legal entity> maintains a quality system certified to the following standards:	Tecan <ajouter une entité juridique> maintient un système de qualité certifié selon les normes suivantes:	Tecan <juristische Person hinzufügen> unterhält ein Qualitätssystem, das nach folgenden Standards zertifiziert ist:	Tecan <aggiungi persona giuridica> mantiene un sistema di qualità certificato secondo i seguenti standard:	A Tecan <adicionar entidade legal> mantém um sistema de qualidade certificado com os seguintes padrões:	Tecan <agregar entidad legal> mantiene un sistema de calidad certificado con los siguientes estándares:
Reviewed by Person Responsible for Regulatory Compliance:	Révisé par la personne responsable de la conformité réglementaire:	Bewertet von der Person, die für die Einhaltung gesetzlicher Vorschriften verantwortlich ist:	Revisionato dal responsabile della conformità normativa:	Revisado pela Pessoa Responsável pela Observância da Documentação:	Revisado por la persona responsable del cumplimiento de la normatividad: