EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

TECAN AUSTRIA GMBH, Untersbergstr. 1A, A-5082 Grödig, Austria

SRN: AT-MF-000020241

for the product:

INFINITE F50 PLUS

Part No.	Model	Configuration
30183570	**Infinite F50 Plus**	**N/A**

Valid from serial number: 2205000001
Embedded Software: V3.33

EMDN: W0201020201 -IMMUNOCHEMISTRY READERS

Basic UDI-DI: 912005207IVS10080000ANZ

Intended purpose:
The INFINITE F50 PLUS is an automated 96-well microplate absorbance reader including Magellan software for professional use in a laboratory for the measurement of light absorbance (optical density) of homogeneous liquid media for in vitro diagnostic use.
The instrument is intended to be used primarily in in-vitro diagnostic analysis of samples from the human body delivered from a user selected Enzyme-linked Assay (ELISA). The specific diagnostic information and type of specimen is defined by the selected assay.
The INFINITE F50 PLUS is intended for the measurement and the evaluation of qualitative, semi-quantitative, and quantitative assays according to scheduled diagnostic parameters and instrument specifications.
The product is intended for professional laboratory use by trained personnel. The product is not for home or lay person use.

The product is in conformity with the provisions of the following European Regulation 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 acc. Rule 2.5 (b)
Conformity assessment procedure: Self declaration according Article 17 (Annex II & 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 61010-2-101: 2017 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

EN 61326-2-6: 2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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

EN 62366: 2008/A1:2015 Medical Device software – Application of usability engineering to medical devices

EN ISO 15223-1: 2020 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: 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 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 Austria GmbH 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 Austria GmbH 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

Reviewed by Person Responsible for Regulatory Compliance:

Bernhard Walter
Senior Manager Regulatory Affairs

2022-05-16
Date

TECAN AUSTRIA GMBH, Untersbergstr. 1A, A-5082 Grödig, Austria, 2022-05-16

Siegfried Sasshofer
Authorized Signatory

Markus Lanschützer
Authorized Signatory

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
the products:	les produits:	die Produkte	i prodotti:	os produtos:	los productos:
the products listed in the Annex of this document	les produits énumérés dans l'annexe de ce document	die im Anhang dieses Dokumentes aufgeführten Produkte	i prodotti elencati nell'allegato del presente documento	os produtos listados no anexo deste documento	los productos enumerados en el Anexo de este documento
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
Configuration	Configuration	Konfiguration	Configurazione	Configuração	Configuración
Software	Logiciel	Software	Software	Software	Software
Options	Les options	Optionen	Opzioni	Opções	Opciones
Valid from serial number or production date:	Valable à partir du numéro de série ou de la date de production:	Gültig ab Seriennummer oder Produktionsdatum	Valido dal numero di serie o dalla data di produzione:	Válido a partir do número de série ou da data de fabrico:	Válido desde el número de serie o la fecha de fabricación:
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:
Common Specifications (CS) used to declare conformity:	Spécifications communes (CS) utilisées pour déclarer la conformité:	Common Specifications (CS) zur Erklärung der Konformität:	Specifiche comuni (CS) utilizzate per dichiarare la conformità:	Especificações comuns (CS) usadas para declarar conformidade:	Especificaciones comunes (CS) utilizadas para declarar conformidad:
Notified Body:	Organisme notifié:	Benannte Stelle:	Organismo notificato	Organismo Notificado:	Organismo notificado:
Certificate Nr.:	N° du certificat:	Zertifikat Nr.	Certificato n .:	Nº do certificado:	Certificado Nº .:
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:
Person authorized to compile the technical file:	Personne autorisée à constituer le dossier technique:	Person, die zur Erstellung der technischen Dokumentation berechtigt ist:	Persona autorizzata a compilare il fascicolo tecnico:	Pessoa autorizada a compilar a documentação Técnica:	Persona autorizada para compilar el archivo técnico:
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:

UK DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

TECAN AUSTRIA GMBH, Untersbergstr. 1A, A-5082 Grödig, Austria

UK Responsible Person: Tecan UK Ltd, Court, 11 – 13 High Street, Theale, Reading, RG7 5AH, United Kingdom

for the product:

INFINITE F50 PLUS

Part No.	Model	Configuration
30183570	**Infinite F50 Plus**	**N/A**

Valid from serial number: 2205000001
Embedded Software: V3.33

GMDN: 57862 Microplate reader IVD, automated

is in conformity with the provisions of the following UK Regulation(s) when installed in accordance with the installation instructions contained in the product documentation:

Medical Devices Regulations 2002

Classification: Other device (all devices except Annex II and self-testing devices)
Conformity assessment procedure: Annex III

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 61010-2-101:2017
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101 : Particular requirements for in vitro diagnostic (IVD) medical equipment.

BS EN 61326-1: 2013
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General 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: 2020
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
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 Austria 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

TECAN AUSTRIA GMBH, Untersbergstr. 1A, A-5082 Grödig, Austria, 2022-05-16

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