TECAN.

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

for the product:

HYDROFLEX

Part No.	Model	Configuration
30087531	**Hydroflex**	**N/A**
30087532	**Hydroflex ELISA**	**N/A**

Valid from serial number: **2205000001**

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 61010-2-081: 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: 2013
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

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 Untersbergstr. 1A A-5082 Grödig, Austria, 2022-05-10

ppa.

Susanne Schröder
Authorized Signatory

Markus Lanschützer
Authorized Signatory

TECAN.

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

for the product:

HYDROFLEX

Part No.	Model	Configuration
30087531	**Hydroflex**	**N/A**
30087532	**Hydroflex ELISA**	**N/A**

Valid from serial number: **2205000001**

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:

The 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 61010-2-081: 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

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Safety of machinery - General principles for design - Risk assessment and risk reduction

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Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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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, Court, 11 – 13 High Street, Theale, Reading, RG7 5AH, United Kingdom

Tecan Austria GmbH Untersbergstr. 1A A-5082 Grödig, Austria, 2022-05-10

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Susanne Schröder
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