

## 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**

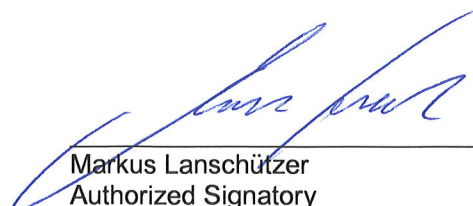
Quality management systems – Requirements

#### **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**

  
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Susanne Schröder  
Authorized Signatory

  
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Markus Lanschützer  
Authorized Signatory

## 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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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:

**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:

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

  
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