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We, **Tecan Schweiz AG, Seestrasse 103, CH-8708 Männedorf**, herewith declare that the product identified as

## Freedom EVOlyzer

is in conformity with the provisions of the following EC Directives when installed in accordance with the installation instructions contained in the product documentation:

**98/79/EC** In Vitro Diagnostic Directive - Annex III

and that the standards referenced below have been applied:

**EN 61010-1:2001** Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use-Part1: General Requirements

**EN 61010-2-101:2002** Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

**EN 61326-1:1997** Electrical Equipment for Measurement, Control and Laboratory Use-  
**+ A1:1998 +A2:2001** EMC Requirements for Emission and Immunity  
**+ A3:2003**

**EN 980:2003** Graphical Symbols for Use in the Labelling of Medical Devices

**EN 1658:1996** Requirements for Marking of in Vitro Diagnostic Instruments

**EN 13485:2003** Medical devices - Quality management systems - Requirements for regulatory purposes

**EN 14971:2000** Medical devices - Application of risk management to medical devices

Equipment covered is listed below.

Base Unit Freedom EVOlyzer 100 / 150 / 200 containing:  
Positive Identification System (PosID 2)  
Loading Interface (Load ITF)  
Robotic Manipulator Arm (RoMa)  
Doorlocks  
Access Status Lamps  
Sensor Pump Option (SPO)  
Room Temperature Incubator  
Frame and Covers

Mandatory Options: 2-Tip / 4-Tip / 8-Tip Liquid Handling Arm (LiHa)  
Worktable for 1 RT-Incubator or  
Worktable for 2 RT-Incubator or  
Worktable for 3 RT-Incubator

This declaration certifies the compliance with the indicated directives, but implies no warranty of properties.

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Sunrise Micro Plate Reader Standard or  
Sunrise Micro Plate Reader Tunable Wavelength  
Columbus Micro Plate Washer 8/16 Manifold or  
Columbus Micro Plate Washer 8/16 Manifold with Fill Verification

Options: Disposable Tip Option  
Lower Disposable Tip Eject Option  
2<sup>nd</sup> Room Temperature Incubator  
Heated Incubator 37°C no shaking  
Heated Incubator 37°C shaking  
Heated Incubator 46°C no shaking  
Heated Incubator 46°C shaking  
Liquid Bottle Trolley  
Wash Bottle Weighing Scale Module  
Disposable Tip Waste Option  
Passive Carrier and Racks  
Shelves with 4, 8, 16, 24, 32 Positions

Equipment covered is listed below.

Models: Instrument Freedom EVOlyzer 100 / 2  
Part No.: 10650100

Models: Instrument Freedom EVOlyzer 100 / 4  
Part No.: 10650101

Models: Instrument Freedom EVOlyzer 150 / 4 / 8  
Part No.: 10650200

Models: Instrument Freedom EVOlyzer 200 / 8  
Part No.: 10650300

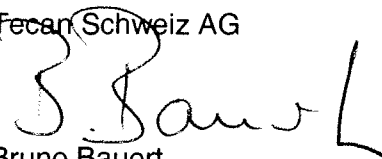
Models: VS Instrument EVOlyzer 150/8 Abbott 4IN  
Part No.: 30024452

Serial No.: > 503000000 (for all models)

Year of CE marking: 2005

Männedorf, 2007-04-12

Tecan Schweiz AG

  
Bruno Bauert  
Head of R & D, Tecan Schweiz AG

  
Thomas Zaugg  
Head of QA, Tecan Schweiz AG