

DECLARATION OF CONFORMITY

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Manufacturer: **Biotektron AG**

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This declaration certifies the conformity of the device with the relevant legal regulations listed below. The manufacturer bears sole responsibility for issuing this EU declaration of conformity.

1 Validity

This declaration is valid for the following products or product variants:

- **Media Preparator PCX** (P/N 1000400)
- **Media Preparator Premium 15** (P/N 1001800)

Intended use: The ProfiClave PCX is a single-user laboratory instrument for the preparation and sterilization of culture media.

2 Parameters

Parameter	Value
Rated voltage	200-240 VAC
Rated frequency	50/60 Hz
Rated power	3500 W
Protection class	I

3 Directives

The subject of the declaration described above complies with the relevant harmonization directives:

EU Directive	Description
2014/35/EU	Low Voltage Directive (LVD)
2014/30/EU	Electromagnetic compatibility (EMC)
2011/65/EU	Use of certain hazardous substances in electrical and electronic equipment (RoHS)
2012/19/EU	Waste electrical and electronic equipment (WEEE)

4 Safety Specifications

The subject of the statement described above meets the following safety requirements:

EU Regulation	Description
1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
EU Standards	Description
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements ■ Safety test based on IEC 61010-1:2010/A1:2016/COR1:2019 ■ Notified body: TÜV SÜD, certificate number: N8A 045076 0001 Rev. 00
EN IEC 61010-2-040:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials ■ Safety text based on IEC 61010-2-040:2015 ■ Notified body: TÜV SÜD, certificate number: N8A 045076 0001 Rev. 00
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

5 Approval and Certificates

Certifier	Certificate No.	Report No.
 TÜV SÜD Product Service GmbH Certification Body Ridlerstrasse 65 80339 Munich Germany	N8A 045076 0001 Rev. 00	713238346

Amriswil, 17.02.2023



Lukas Krüsi
CEO