Prestige Medical
PART OF Tuttnauer LTD.

EU Declaration of Conformity Date: 27/02/2023

Declaration of Conformity

for Autoclave - 2100 Series

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Classic Autoclave
Legal Manufacturer:	**PRESTIGE MEDICAL LIMITED** East House, Duttons Way, Shadsworth Business Park, Blackburn. Lancashire. BB1 2QR. ENGLAND Tel: + 44 (0) 1254 682622 Fax: +44 (0) 1254 682606 E-mail: sales@prestigemedical.co.uk
EU Authorised Representative:	Tuttnauer Europe b.v., Hoeksteen 11, 4815 PR Breda, P.O. Box 7191, 4800 GD Breda, The Netherlands
Intended Use:	The 2100 series Classic autoclave is designed for the sterilization of dental, medical and other types of surgical instruments to prevent cross infection
MDD Classification:	Class II(b)
Notified Body:	BSI NL 2797
CE Certificate Reference:	CE 01354
MDD Conformity Assessment Route:	Annex II excluding section 4
Additional Information	ISO13485:2016 Accredited Quality System

Name John Potter **Position** Managing Director

Signed  **Date** 03/04/2023

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
UK MDR Part II 2002	UK Medical Device Regulations (MDR) Part II 2002
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
BS EN 13060:2014 + A1: 2018	Small Steam Sterilizers
BS ISO 16528-1: 2007	Boilers and Pressure Vessels: Performance Requirements
EN 61010-1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use
EN 61010-2-040:2020	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
ROHS 2011/65/EU	The restriction of the use of certain hazardous substances in electrical and electronic equipment
ROHS 2015/863/EU	Amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	EMDN Code
210001	Standard 9 litre 230V, 50-60Hz	S9099
210004	Extended 12 litre with gauges 230V, 50-60Hz	S9099
210048	Extended 12 litre Media 230V, 50-60Hz	S9099
210052	Standard 9 litre Podiaclave 230V, 50-60Hz	S9099

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Revision History

Revision	Compiled by	Date	Description
01	K Marrow	14/12/2020	New Document
02	J. Lane	15/02/2022	Addition of EC EU Rep
03	J. Lane	13/06/2022	Addition of 61010-1 and 61010-2-040
04	J. Lane	27/02/2023	Change of EC EU Rep
05	J. Lane	03/04/2023	Updates in applicable standards