

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: <u>sales@prestigemedical.co.uk</u>	
EU Authorised Representative:		
Intended Use:	The 2100 series Classic autoclave is designed for the sterilization ontended Use: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:	icate 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	Abbler	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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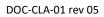
Appendix I – Applicable Standards

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	
EN 130 13483.2010	for Regulatory Purposes	
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical	
EN 130 14971.2019	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	
	Amending Annex II to Directive 2011/65/EU of the European	
ROHS 2015/863/EU	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	210004 Extended 12 litre with gauges 230V, 50-60Hz	
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