Prestige Medical
Integrated Decontamination Solutions

EU Declaration of Conformity Date: 17/12/2020

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
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:	CE01354
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	ISO13485:2016 Accredited Quality System

Name John Potter **Position** Managing Director

Signed **Date** 17/12/2020

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
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 14971:2012	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 16528-1: 2007 and BS 16528-2: 2007	Boilers and Pressure vessels. Requirements

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
210001	Standard 9 litre 230V, 50-60Hz	40547
210002	Extended 12 litre 230V, 50-60Hz	40547
210004	Extended 12 litre with gauges 230V, 50-60Hz	40547
210006	Standard 9 litre 120V, 50-60Hz	40547
210007	Extended 12 litre Media 120V, 50-60Hz	40547
210011	Standard 9 litre with cassettes 230V, 50-60Hz	40547
210025	Standard 9 litre Media 120V, 50-60Hz	40547
210045	Standard 9 litre Aptum 230V, 50-60Hz	40547
210047	Standard 9 litre Media 230V, 50-60Hz	40547

210048	Extended 12 litre Media 230V, 50-60Hz	40547
210050	Standard 9 litre Aptum 120V, 50-60Hz	40547
210052	Standard 9 litre Podiaclave 230V, 50-60Hz	40547
210134	Standard 9 litre 134 Model 230V, 50-60Hz	40547

Version History

Version	Compiled by	Date	Description
1.0	K Marrow	14/12/2020	New Document
2.0	R Parker	20/09/2021	Second edition