

Prestige Medical

PART OF Tuttnauer LTD.

EU Declaration of Conformity as per 2014/35/EU Low Voltage Directive & 2011/65/EU RoHS in electrical and electronic equipment

for Steam Steriliser – 2100 T-Classic Product Range

| Manufacturer: | PRESTIGE MEDICAL LIMITED |
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| | East House, Dutton's 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: | Tuttnauer Europe BV., Hoeksteen 11, 4815 PR Breda, P.O. Box 7191, 4800 GD Breda, The Netherlands |
| Product: | 210001 T-Classic One |
| | 210004 T-Classic Plus |
| | 210048 T-Classic Media |
| | 210052 T-Classic Podiaclave |
| Standards Applied: | 2014/35/EU - Low Voltage Directive |
| | 2011/65/EU - RoHS electrical and electronic equipment |
| | 2014/30/EU - Electromagnetic Compatibility Directive |
| | BS EN 13060:2014 + A1: 2018 - Small Steam Sterilizers |
| | BS ISO 16528-1: 2007 -Boilers and Pressure Vessels: Performance Requirements |
| | EN 61010-1:2010/A1:2019 - Safety requirements for electrical equipment for measurement, control, and laboratory use |
| | EN 61010-2:2020 - 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. |
| | EN IEC 61326-1:2021 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (IEC 61326-1:2020) |
| • | the T-Classic product range meets the requirements of the 2014/35/EU directive , fulfils the safety in article 3 as set out in Annex I of this directive, and therefore qualifies for free movement within markets |

objectives referred to in article 3 as set out in Annex I of this directive, and therefore qualifies for free movement within markets comprising the European Union (EU) and the European Economic Area (EEA). This declaration is issued under the sole responsibility of the manufacturer. The T-Classic product range also meets the requirements of the **2011/65/EU directive** for the restriction of use of certain hazardous substances in electrical and electronic equipment.

Name:

John Potter

Position:

Managing Director

Signature:

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Place, Date of Issue:

England (UK), 27 February 2024

as per 2014/35/EU & 2011/65/EU