EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01354**

Issued To: **Prestige Medical Limited**
East House
Duttons Way
Shadsworth Business Park
Blackburn
BB1 2QR
United Kingdom

In respect of:

The design and manufacture of autoclaves for medical and dental use.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1996-07-11** Date: **2019-10-15** Expiry Date: **2023-02-27**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01354**
Date:	**2019-10-15**
Issued To:	**Prestige Medical Limited** **East House** **Duttons Way** **Shadsworth Business Park** **Blackburn** **BB1 2QR** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Advena Limited Tower Business Centre 2nd Flr. Tower Street Swatar BKR 4013 Malta	**EU Representative**

...making excellence a habit.™

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01354**

Date: **2019-10-15**

Issued To: **Prestige Medical Limited**
East House
Duttons Way
Shadsworth Business Park
Blackburn
BB1 2QR
United Kingdom

Date	Reference Number	Action
11 July 1996		Original Issue
27 February 2003		Re-issued to update to new certificate format and to remove reference to servicing in the scope, which is not appropriate for an EC certificate.
14 February 2008	7005291	Certificate Renewal
24 August 2009	7417143	Certificate re-issue due to address change
27 August 2012	7880185	Certificate Reinstatement
18 February 2013	7768212	Certificate renewal. Scope clarification: - duplicate term removed ('steam sterilisers') -'development' removed for standardisation purposes
23 February 2018	8869547	Certificate renewal. Addition of Shenzhen OXY Generator Technology Development Co. Ltd. as a significant subcontractor for manufacture.
15 October 2019	7780150	Traceable to NB 0086.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
21 July 2022	3684005	Addition of EU representative to Advena Limited and removal of subcontractor - Shenzhen Oxy Generator Technology Development Co. Ltd., Shenzhen, China.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Inspiring trust for a more resilient world.

21 July 2022

Prestige Medical Limited
East House
Duttons Way
Shadsworth Business Park
Blackburn
BB1 2QR
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related or MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 01354	93/42/EEC Annex II excluding Section 4	3684005	Addition of EU representative to Advena Limited and removal of subcontractor - Shenzhen Oxy Generator Technology Development Co. Ltd., Shenzhen, China.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com bsigroup.nl

By Royal Charter

SUSTAINABLE DEVELOPMENT GOALS

Prestige Medical
PART OF Tuttnauer LTD.

East House
Duttons Way
Shadsworth Business Park
Blackburn
Lancashire
BB1 2QR

Date: 12/12/2023

Re: Active MDR application with our Notified body

Dear valued customer,

Prestige Medical works closely with customers, distributors, importers, and suppliers, to deliver high quality and regulatory compliant devices to various markets worldwide.

Prestige Medical currently hold a CE certificate, ref CE 01354, which expired on 27th February 2023. This letter is to confirm that although the certificate has expired, Prestige Medical are in an active MDR application with our notified body. The aim of this application is to conform to regulation EU 2017/745.

Prestige Medical also hold an article 97 derogation letter issued by a European Competent authority which grants extension of the activities set out in the CE certificate with reference CE 01354. The derogation expires March 2024 but will be automatically renewed if MDR is not given before this date.

This enables Prestige Medical to place the CE mark on their products for sale into the European market.

Please note that this only applicable to the Classic product family.

If you require further information, feel free to contact the Prestige Medical Quality department.

Kind Regards

Jonathan Lane
QA RA & Engineering Manager