

EC Certificate - Full Quality Assurance System

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

No.**CE 556743****Issued To:**

**B & D Electromedical Limited
Units A1-A2
The Bridge Business Centre
Timothy's Bridge Road
Stratford Enterprise Park
Stratford-upon-Avon
CV37 9HW
United Kingdom**

In respect of:

Design and manufacture of patient ventilators, airway clearance devices and their associated breathing circuits

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **10 November 2010**

Date: **22 October 2015**

Expiry Date: **09 November 2020**

...making excellence a habit.™

Page 1 of 1

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.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 556743**
Date: **22 October 2015**
Issued To: **B & D Electromedical Limited**
Units A1-A2
The Bridge Business Centre
Timothy's Bridge Road
Stratford Enterprise Park
Stratford-upon-Avon
CV37 9HW
United Kingdom

Date	Reference Number	Action
10 November 2010	7457882	First Issue
30 November 2010	7611647	Reissue to include airway clearance devices within the scope
22 October 2015	8349718	Certificate Renewal

...making excellence a habit.™

Page 1 of 1

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.