



## EC Certificate - Full Quality Assurance System

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

No. CE 01847

Issued To: Therapy Equipment Ltd

**Unit 1 Cranbourne Avenue Cranbourne Industrial Estate** 

Potters Bar Hertfordshire EN6 3JN

**United Kingdom** 

In respect of:

The design and manufacture of gas regulators, flowmeters, vacuum equipment, demand valves and hose assemblies

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):

Stewart Brain, Head of Compliance & Risk -

**Medical Devices** 

First Issued: **1998-03-12** Date: **2018-03-06** Expiry Date: **2023-03-11** 

...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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.

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 01847** 

Date: **2018-03-06** 

Issued To: Therapy Equipment Ltd

Unit 1 Cranbourne Avenue Cranbourne Industrial Estate

Potters Bar Hertfordshire EN6 3JN

**United Kingdom** 

## **Certificate History**

Date	Reference Number	Action
12 March 1998		First Issue
10 June 1998		Change of scope
09 July 1998		Change of scope
27 April 2001		Change of scope
15 December 2003		Five Years Renewal
		New Certificate format
03 March 2008	7172348	Certificate Renewal
01 March 2013	7915329	Certificate Renewal
		Change of scope and upgrade to an Annex II
Current	8893382	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.