

EC Certificate Full Quality Assurance System: Certificate US10774611

The management system of

Bolton Medical, Inc.

799 International Parkway, Sunrise, FL, 33325, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

**Treovance Abdominal stent-graft with Navitel Delivery System
and TREO Abdominal Stent-Graft System
TREO AUI Stent-Graft System
TREO Occluder System**

- 1) RELAY Thoracic Stent-Graft with Transport Delivery System
- 2) RELAY Plus Thoracic Stent-Graft with Delivery System
- 3) RELAY NBS Plus Thoracic Stent-Graft with Delivery System
- 4) RelayPro Thoracic Stent-Graft System (Bare Stent Configuration)
- 5) RelayPro Thoracic Stent-Graft System (NBS Configuration)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 March 2019 until 18 March 2024
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 March 2022
Issue 6. Certified since 19 March 2010

Certification is based on reports numbered WW/MC 08021

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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