



By Royal Charter

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 592088**  
Issued To: **Laborie Medical Technologies Canada ULC**  
**6415 Northwest Drive, Unit 10**  
**Mississauga**  
**Ontario**  
**L4V 1X1**  
**Canada**

In respect of:

**The design and manufacture of: urodynamic diagnostic and therapeutic devices and sterile tubing; diagnostic ultrasound devices, sterile endoscopic needles and sterile accessories.**

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: **2012-12-21**

Date: **2017-08-02**

Expiry Date: **2022-08-02**

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
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