

# EC Certificate - Full Quality Assurance System

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

No.

**CE 01806**

Issued To:

**Medtronic Powered Surgical Solution  
4620 North Beach Street  
Fort Worth  
Texas  
76137  
USA**

In respect of:

**The design and manufacture of pneumatic and electric motors, motor attachments, dissecting tools and motor set-up accessories for surgical use supplied sterile and non-sterile. Those aspects of Annex II related to securing sterility in the manufacture of bone mill disposable devices.**

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):



Gary Fenton, Global Assurance Director

First Issued: **13 January 1998**

Date: **21 October 2014**

Expiry Date: **12 January 2018**

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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.