By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 632579**

Issued To: **Patient Pocket, LLC**
405 Hialeah Drive
Cherry Hill
New Jersey
08002
USA

In respect of:

Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture surgical laser fiber docking stations.

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: **30 November 2015** Date: **30 November 2015** Expiry Date: **29 November 2020**

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 632579**
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Subcontractor:	**Service(s) supplied**
DSM Biomedical 735 Pennsylvania Drive Exton Pennsylvania 19341 USA	**Manufacture**
Medes Limited 5 Beaumont Gate Shenley Hill Radlett Hertfordshire WD7 7AR United Kingdom	**EU Representative**
STERIS Isomedix Services 1880 Industrial Drive Libertyville IL 60048 USA	**Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
30 November 2015	8295533	First Issue

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