

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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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.

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List of Significant Subcontractors

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

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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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Page 1 of 1

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