EC Certificate - Full Quality Assurance System

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

No. **CE 577865**

Issued To: **Protek Medical Products, Inc.**
4125 Westcor Court
Coralville
Iowa
52241
USA

In respect of:

See certificate scope page.

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-09-01** Date: **2019-05-09** Expiry Date: **2024-05-01**

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By Royal Charter

Certificate No: CE 577865

Certificate Scope:

Design, development and manufacture of:
- Sterile Single-use General Purpose Probe and Instrument covers for surgical procedures
- Kits for ultrasound & imaging procedures containing:
• Sterile Single-use General Purpose Probe and Instrument covers for surgical procedures
• Single-use Endocavity Probe Covers with respect to body orifices
• Single-use Endocavity Needle Guides with respect to body orifices
• Non-invasive Single-use General Purpose Needle Guides
• Single-use System Drapes
• Conductive gels for ultrasound procedures

Those aspects of Annex II concerned with securing and maintaining sterile conditions of:
- Single-use Endocavity Probe Covers with respect to body orifices
- Single-use Endocavity Needle Guides with respect to body orifices
- Non-invasive Single-use General Purpose Needle Guides
- Single-use System Drapes

First Issued: **2011-09-01** Date: **2019-05-09** Expiry Date: **2024-05-01**

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Supplementary Information to CE 577865

Issued To:

Protek Medical Products, Inc.
4125 Westcor Court
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Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG SMD0106	Sterile Single-use General Purpose Probe and Instrument covers for surgical procedures	Medical device used over imaging probes or instruments to provide a sterile protection, and to minimize cross contamination during diagnostic imaging procedures.
NBOG SMD0106	Kits for ultrasound & imaging procedures	Medical device used over imaging probes or instruments to provide a sterile protection, and to minimize cross contamination during diagnostic imaging procedures. Medical device used to provide precise needle placement to an intended target assisting healthcare professionals performing needle/instrument guided imaging procedures.
Class Is		
NBOG SMD0106	Single-use Endocavity Probe Covers	Medical device used over imaging probes or instruments to provide a sterile protection, and to minimize cross contamination during diagnostic imaging procedures.

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Number	Device Name	Intended purpose per IFU
Class Is		
NBOG SMD0106	Single-use System Drapes	Medical devices used as sterile protective covering for imaging systems, cords, monitors, and keyboards during diagnostic imaging procedures to minimize cross contamination.
NBOG SMD0106	Single-use Endocavity Needle Guides	This is a medical device used to provide precise needle placement to an intended target assisting healthcare professionals performing needle/instrument guided imaging procedures.
NBOG SMD0106	Non-invasive Single-use General Purpose Needle Guides	This is a medical device used to provide precise needle placement to an intended target assisting healthcare professionals performing needle/instrument guided imaging procedures.

First Issued: **2011-09-01** Date: **2019-05-09** Expiry Date: **2024-05-01**

By Royal Charter

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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 577865**
Date:	**2019-05-09**
Issued To:	**Protek Medical Products, Inc.** **4125 Westcor Court** **Coralville** **Iowa** **52241** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Parker Laboratories, Inc. 286 Eldridge Road Fairfield New Jersey 07004 USA	**Manufacture**
Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527 USA	**ETO Sterilization**

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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 577865**
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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 577865**

Date: **2019-05-09**

Issued To: **Protek Medical Products, Inc.**
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Date	Reference Number	Action
01 September 2011	7719323	First issue. Transfer from another Notified Body, NEMCO, certificate references EU0904412, EU0904413, EU0904414, EU0904415 and EU0904416.
30 April 2014	8110764	Certificate renewal; Addition of reusable needle guides to the scope; Change of EU Rep.
12 December 2017	8743320	EU representative address change.
21 February 2019	7781588	Traceable to NB 0086.
Current	9749187	Certificate renewal, scope update, addition of subcontractors Sterigenics US, LLC in Queensbury, USA for ETO Sterilization and Parker Laboratories, Inc. in Fairfield, USA for Manufacture.