By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 676122**

Issued To: **Checkpoint Surgical, Inc.**
6050 Oak Tree Blvd, Suite 360
Independence
Ohio
44131
USA

In respect of:

Design and manufacture of sterile intraoperative neurostimulation 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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-06-07** Date: **2021-05-25** Expiry Date: **2023-06-06**

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Supplementary Information to CE 676122

Issued To:

Checkpoint Surgical, Inc.
6050 Oak Tree Blvd, Suite 360
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44131
USA

NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 1103	9094 Checkpoint Surgical Stimulator	---
MD 1103	9394 Checkpoint Head and Neck Stimulator	---

First Issued: **2018-06-07** Date: **2021-05-25** Expiry Date: **2023-06-06**

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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 676122**
Date:	**2021-05-25**
Issued To:	**Checkpoint Surgical, Inc.** **6050 Oak Tree Blvd, Suite 360** **Independence** **Ohio** **44131** **USA**

Subcontractor:	**Service(s) supplied**
Centurion Medical Products Corporation 301 Catrell Drive Howell, MI 48843 USA	**ETO Sterilization**
Isomedix Operations, Inc. A division of Steris Applied Sterilization Technologies (AST) 2072 Southport Road Spartanburg SC 29306 USA	**ETO Sterilization**
Robling Medical, Inc. 90 Weathers Street Youngsville NC 27596 USA	**Manufacture**

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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 676122**
Date:	**2021-05-25**
Issued To:	**Checkpoint Surgical, Inc.** **6050 Oak Tree Blvd, Suite 360** **Independence** **Ohio** **44131** **USA**

Subcontractor:	**Service(s) supplied**
WMDE B.V. Bergerweg 18, Holland 6085 AT Horn The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 676122**

Date: **2021-05-25**

Issued To: **Checkpoint Surgical, Inc.**
6050 Oak Tree Blvd, Suite 360
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44131
USA

Date	Reference Number	Action
07 June 2018	8759393	First Issue.
22 February 2019	8893351	Traceable to NB 0086.
14 October 2019	9786158	Added ETO sterilization subcontractor: Isomedix Operations, Inc. 2072 Southport Road, Spartanburg, SC 29306.
Current	3445440	Modified legal manufacturer address from "22901 Millcreek Boulevard, Suite 360, Cleveland, Ohio 44122 USA" to "6050 Oak Tree Blvd, Suite 360, Independence, Ohio 44131 USA". Added device information table to certificate.