

# 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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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

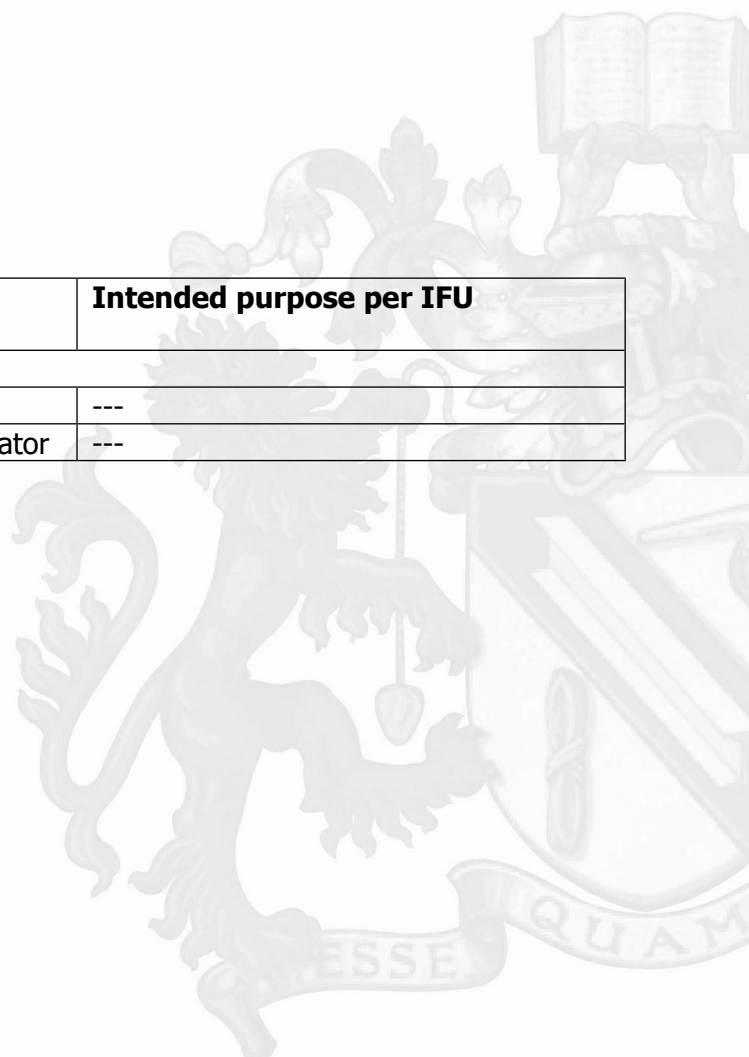
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## Supplementary Information to CE 676122

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



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## List of Significant Subcontractors

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

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

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**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**  
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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.