

EC Certificate - Full Quality Assurance System

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

No.**CE 656684**

Issued To:

**ClaroNav Kolahi Inc.
1140 Sheppard Avenue. West, Unit 10
Toronto
Ontario
M3K 2A2
Canada**

In respect of:

Design and manufacture of Navient image guided ENT and Cranial Navigation system and accessories.

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: **2016-11-11**Date: **2021-05-21**Expiry Date: **2024-05-26**

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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.

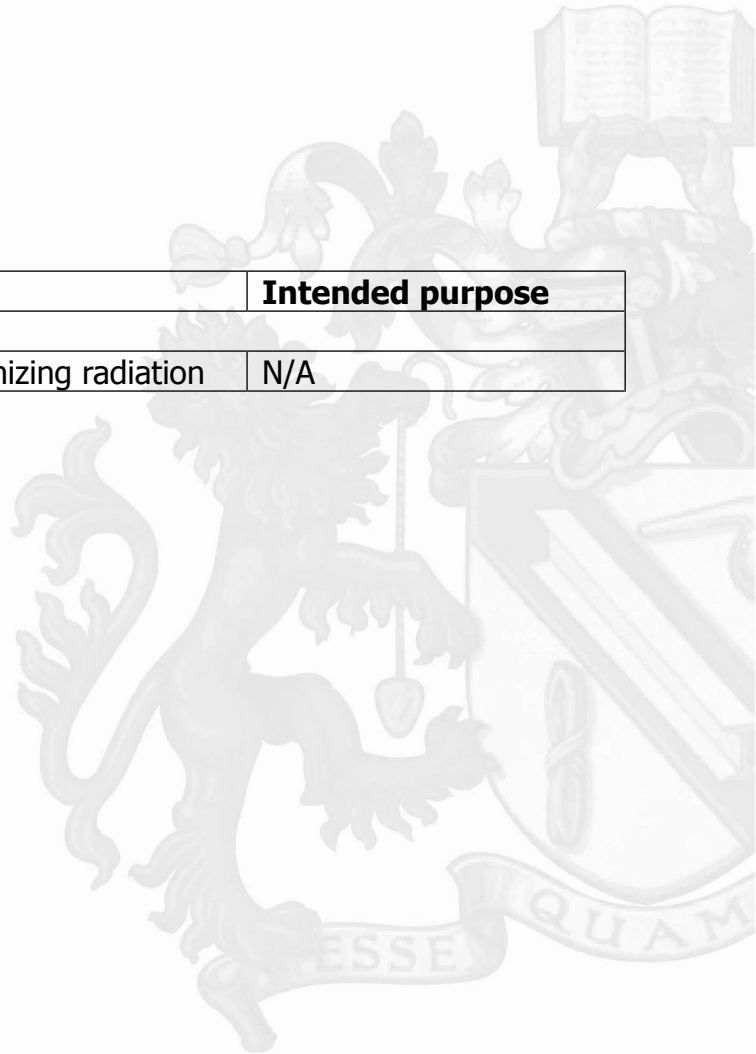
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Supplementary Information to CE 656684

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NBOG Code	Device description	Intended purpose
Class IIa		
MD 1202	Imaging devices utilising non-ionizing radiation	N/A



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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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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

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Certificate History

Certificate No: **CE 656684**
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Date	Reference Number	Action
11 November 2016	8559124	First Issue
15 August 2017	8779410	Change of EU Representative address from Emergo Group B.V Molentraat 15, The Hauge, 2513 BH, Netherlands to Emergo Europe, Prinsessegracht 20, 2514 AP The Hauge, The Netherlands
28 February 2019	9630615	Traceable to NB 0086.
Current	9786807	Certificate renewal. Device table added.