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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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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 656684**

Date: **2021-05-21**

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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.
21 May 2021	9786807	Certificate renewal. Device table added.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 October 2023	30004845	Change of EU Authorised Representative address. Removal of Subcontractor pages.

Inspiring trust for a more resilient world.

20 October 2023

ClaroNav Kolahi Inc.
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 656684	93/42/EEC Annex II excluding Section 4	30004845	Change of EU Authorised Representative address. Removal of Subcontractor pages.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices