By Royal Charter

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):

Albert Roossien, Regulatory Lead

First Issued: **2016-11-11** Date: **2019-02-28** Expiry Date: **2021-11-10**

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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 656684**
Date:	**2019-02-28**
Issued To:	**ClaroNav Kolahi Inc.** **1140 Sheppard Avenue. West, Unit 10** **Toronto** **Ontario** **M3K 2A2** **Canada**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance System 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
Current	9630615	Traceable to NB 0086.