ClaroNav Kolahi Inc.
1140 Sheppard Ave. West, Unit 10
Toronto, Ontario, Canada M3K 2A2
Tel. 1-647-951-1525, Fax 1-647-951-1524
www.claronav.com

Valid as of August 5, 2020

Declaration of Conformity

This declaration is made in accordance with Medical Device Directive 93/42/EEC, Annex II

Name and Address of the Manufacturer:
ClaroNav Kolahi Inc.
1140 Sheppard Ave. West, Unit 10
Toronto, Ontario, CANADA, M3K 2A2
Ahmad Kolahi - CEO - ahmad@claronav.com

Name and Address of Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299
Web: http://www.emergogroup.com/

Identification of the Device: Navient System Model # 955-NE-NE, # 955-NC-NC

Name and Address of Notified Body:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Country : Netherlands
Phone : +31 (0)20 346 07 80
Email : info.nl@bsigroup.com

Notified Body number: 2797

Certificate Number (issued by BSI): CE 656684

Classification of the device: Class IIa (as per Rule 9)

Compliance with Annex II (excluding section 4) of the Medical Device Directive, Council Directive 93/42/EEC

ClaroNav Kolahi Inc. declares that Navient bears the CE mark of conformity and complies with the requirement of council directive of 93/42/EEC for Medical Devices. All supporting documentation is retained at the premises of the manufacturer.

This Declaration of Conformity covers the products listed in Appendix A which bears the CE mark of Conformity and is distributed by ClaroNav Kolahi Inc. in accordance to the Medical Device Directive.

I, the undersigned, hereby declare that the products identified in Appendix A conforms to the above Medical Device Directive.

Company's Representative:

Signature:

Name: Ahmad Kolahi

Title: CEO

Date: August 5, 2020

Appendix A- Navient Product List

This product list specifies the Navient products bearing the CE Mark distributed by ClaroNav Kolahi Inc. in accordance to the EU Medical Device Directive:

Product Model	**REF**	**Initial Serial Number**
Navient System (ENT configuration)	955-NE-NE	1601
Navient System (Cranial configuration)	955-NC-NC	2001
Patient Tracker	950-NE-PT	Not Applicable
Universal Tracker Biopsy	950-NC-UTB	Not Applicable
Universal Tracker Cusa	950-NC-UTC	Not Applicable
Universal Tracker Stimulation probe	950-NC-UTSP	Not Applicable

ClaroNav Kolahi Inc.
1140 Sheppard Ave. West, Unit 10
Toronto, Ontario, Canada M3K 2A2
Tel. 1-647-951-1525, Fax 1-647-951-1524
www.claronav.com

March 28, 2024

Addendum

NOTE: the following Navient models described in the Declaration of Conformity dated August 5, 2020 include the following accessory kits:

- Navient System (ENT configuration), 955-NE-NE includes:
  - ENT Accessory Kit, 955-NE-ACCK (and optional set B 955-NE-ACCK-B)
- Navient System (Cranial configuration), 955-NC-NC includes:
  - Cranial Accessory Kit, 955-NC-AKC
  - Biopsy Accessory Kit, 955-NC-AKB
  - ENT Accessory Kit, 955-NE-ACCK

Below is a list of non-significant changes to the Navient Declaration of Conformity issued on August 5, 2020.

- Change 1 (submitted to NB May 25, 2023): Name and Address of the Authorized Representative, applicable as of January 31, 2023:
  Emergo Europe
  Westervoortsedijk 60
  6827 AT Arnhem
  The Netherlands
  Tel: (31) (0) 70 345-8570

- Change 2 (submitted to NB August 14, 2023): Addition of instruments modified from existing instruments (Spine Accessory Kit, 955-NS-ACCK) and introduction of additional sub-stage to plan vertebra screw trajectory in the software

- Change 3 (acknowledged by incoming NB and exiting NB March 19, 2024): change of Notified Body from BSI to Intertek.

Company's Representative:

Signature: A. Kolahi

Name: Ahmad Kolahi
Title: CEO, ClaroNav Kolahi Inc.

Date: Mar 28, 2024