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 July 22, 2022

## 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: July 22, 2022

**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 |
| Cranial Accessory kit | 955-NC-AKC | 2001 |
| Biopsy Accessory kit | 955-NC-AKB | 2001 |
| ENT Accessory Kit | 955-NE-ACCK | 1601 |
| 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 |