Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of ClaroNav Inc. in compliance with Article 19 of EU MDR 2017/745 and Article 13 of Directive 2011/65/EU (RoHS). We hereby declare that the medical device specified in this document meets the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices and Directive 2011/65/EU on the restriction of the use of certain hazardous substance in electrical and electronic equipment.

1 Information regarding the Manufacturer, Authorized Representative and Notified Body

Manufacturer Name:	ClaroNav Inc.
Manufacturer address:	1140 Sheppard Ave West, Unit 10 Toronto, Ontario, Canada M3K 2A2
Manufacturer SRN:	CA-MF-000028837
Authorized representative Name and address:	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands Phone: +31.70.345.8570 EmergoEurope@ul.com
Authorized Representative SRN:	NL-AR-000000116
Notified Body:	Intertek Medical Notified Body AB Torshamnsgatan 43 Box 1103 SE-164 22 Kista Sweden Notified Body Designation: 2862
Conformity assessment Route:	MDR article 52 and Annex IX, Conformity assessment based on a quality management system and on assessment of technical documentation.
Certificate Number (issued by Intertek):	28620194069

2 Device Related Information

Device/s Name:	Navident (Model #:955-ND-ND), including the following configurations/variants:

Name	Configuration Details	REF/Catalog #
Navident EVO Cart	Navident System (Model #:955-ND-ND), cart configuration	955-ND-ND-201
Navident EVO Mount	Navident System (Model #:955-ND-ND), mounted configuration	955-ND-ND-202

Basic UDI:	7540209955-ND-NDUL
Catalogue Number:	*See table above.*
Device Classification:	Class IIa
Classification Rule:	Rule 11
Intended purpose:	Navident is a dental navigation system intended to assist preoperative planning and real-time positioning of tools during dental procedures, when a pre-acquired CT scan of the jaw is available. In particular, it provides visual real-time feedback on the location of the active tip of a dental handpiece and its direction relative to a volumetric CT image of the patient's jaw anatomy registered to that anatomy, and, when a path has been planned, relative to a path planned on that image. It is intended to be used by a qualified dental surgeon as an optional aid.
Common Specifications	N/A – No common specifications are relevant to the products covered by this declaration.

The accessories to the Navident System are classified as Class I and have been CE-marked by self-declaration of conformity under Medical Device Regulation (EU) 2017/745. The technical documentation and Declaration of Conformity for these devices are maintained under Technical Documentation #:985-09012.

3 Statement

We, ClaroNav Inc., hereby declare, under our sole responsibility, that the devices specified here conform to the EU Medical Device Regulation 2017/745 and Directive 2011/65/EU (RoHS) that provides for the issuing of an EU Declaration of Conformity.

Signature: 

Name: Carly Desmond

Role: Director of Regulatory Affairs

Place of Issue: Toronto, Ontario, Canada

Date of Issue: October 21, 2024