Document number: 960-09138

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of ClaroNav Inc. in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified in this document meet the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices.

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:	N/A – Class I, self-certified.
Conformity assessment Route:	Regulation (EU) 2017/745: Technical Documentation (Annex II and III) and Annex IV, Declaration of Conformity (Class I, self-certified)
Certificate Number (issued by BSI/Intertek):	NA- Class I

2 Device Related Information

Device/s Name:	Navident Procedure Kit — 955-ND-PRK Navident Accessory Kit — 955-ND-ACCK *Note: For the purpose of conformity assessment, each of the above kits have been treated as a system.*
Basic UDI:	7540209955-ND-KITSCP
Catalogue Number:	*See Table above*
Device Classification:	Class I
Classification Rule:	Rule 1 and Rule 5
Intended purpose:	Accessories to Navident medical device: 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

3 Statement

We, ClaroNav Inc. hereby declare, under our sole responsibility, that the Accessories specified here conform to the EU Medical Device Regulation 2017/745 that provides for the issuing of an EU Declaration of Conformity.

Signature:

Name: Carly Desmond

Role: Director of Regulatory Affairs

Place of issue: Toronto

Date of Issue: June 19, 2023