



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 devices specified in this document meet the requirements of 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 (as applicable).

This Declaration of Conformity applies to the MicronMapper configurable device covered under Basic UDI-DI 7540209955-ND-MMV3. MicronMapper is composed of multiple medical devices and accessories, including the MicronMapper Camera, MicronMapper Software, and MicronMapper Scan Bodies, as identified in Table 1 and Appendix A.

Each of these devices and accessories is regulated under Regulation (EU) 2017/745 and classified in its own right in accordance with Annex VIII. The MicronMapper Scan Bodies and associated bases are accessories intended to be used together with the MicronMapper devices identified in Table 1.

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:	MicronMapper (devices and accessories listed in Table 1)	
Basic UDI:	7540209955-ND-MMV3	
Device Classification and Annex VIII Rule:	MicronMapper Software: Class I, Rule 11 MicronMapper Camera: Class I, Rule 13 MicronMapper Scan Bodies and associated bases: Class I, Rule 5	
Intended purpose:	MicronMapper is an optical metrology system intended for measuring the relative positions of abutments attached to implants placed in a human jaw. MicronMapper assists in the design of temporary or final full arch prostheses by capturing and analyzing positional data from video images, the output of which is then entered into other commercially available dental prosthesis design software programs. The system is intended to be operated by a licensed dental clinic or lab staff member. The data provided by MicronMapper is not intended for use as an aid in diagnostic or therapeutic decision making.	
Model Number	Description	Date of Original CE-marking
955-MM1-MSSM-ASY	MicronMapper System, with: - MicronMapper Camera - MicronMapper Software - Scan Bodies	August 2024
955-MME-ESSM-ASY	MicronMapper EVO System, with: - MicronMapper Software - MicronMapper EVO Scan Bodies	August 2024

Table 1. Devices and Accessories Covered by this Declaration of Conformity and Identification of Applicable EU Regulations/Directives.

Model Number	Device/ Accessory Name	Class/Rule	Applicable EU Regulations or Directives	Date of Original CE-marking
50BL-12L-1S	MicronMapper Camera	Class I, Rule 13	1) Regulation (EU) 2017/745 2) 2011/65/EU (RoHS)	August 2024
990-MM1-INST-WIN	MicronMapper Software	Class I, Rule 11	Regulation (EU) 2017/745	August 2024
950-MM1-SCAN-BDY	MicronMapper Scan Bodies	Class I, Rule 5	Regulation (EU) 2017/745	August 2024



955-MM1-SPLT-BDY	MicronMapper Split Scan Bodies	Class I, Rule 5	Regulation (EU) 2017/745	May 2025
950-MME-SCAN-BDY	MicronMapper EVO Scan Bodies	Class I, Rule 5	Regulation (EU) 2017/745	August 2024
955-MME-SPLT-BDY	MicronMapper EVO Split Scan Bodies	Class I, Rule 5	Regulation (EU) 2017/745	May 2025
955-MM1-SS16-BDY	MicronMapper Split Scan Bodies (1.6 mm)	Class I, Rule 5	Regulation (EU) 2017/745	May 2026
955-MME-SS16-BDY	MicronMapper EVO Split Scan Bodies (1.6 mm)	Class I, Rule 5	Regulation (EU) 2017/745	May 2026
955-MM1-SMNI-BDY	MicronMapper Split Scan Bodies (Mini)	Class I, Rule 5	Regulation (EU) 2017/745	May 2026
950-MM1-SLOC-BDY	MicronMapper Locator Scan Bodies	Class I, Rule 5	Regulation (EU) 2017/745	May 2026
950-MM1-SS14-BSE	MicronMapper Split Scan Body Bases (1.4mm)	Class I, Rule 5	Regulation (EU) 2017/745	May 2026
950-MM1-SS16-BSE	MicronMapper Split Scan Body Bases (1.6mm)	Class I, Rule 5	Regulation (EU) 2017/745	May 2026
950-MM1-SMNI-BSE	MicronMapper Split Scan Body Bases (Mini)	Class I, Rule 5	Regulation (EU) 2017/745	May 2026

For a complete list of sales configurations and catalog numbers, see Appendix A.

3 Statement

We, ClaroNav Inc. hereby declare, under our sole responsibility, that the devices identified above conform to the EU Medical Device Regulation 2017/745 and Directive 2011/65/EU (RoHS) (as specified in Table 1), which provide requirements for the issuing of an EU Declaration of Conformity.

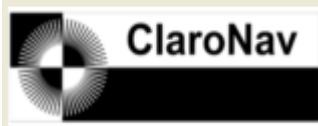
Signature:

Name: Carly Desmond

Role: Director of Regulatory Affairs

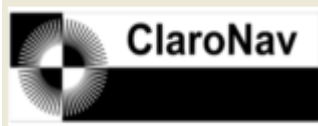
Place of issue: Toronto

Date of Issue: May 21, 2026



Appendix A – List of Sales Configurations and Catalog Numbers

Base Model	Variant Type	REF/Catalog number
MicronMapper System 955-MM1-MSSM-ASY	MicronMapper System with Unlimited Plan and Unibody Scan Bodies	955-MM1-MSSM-ASY-A
	MicronMapper System with Unlimited Plan and Split Scan Bodies	955-MM1-MSSM-ASY-B
	MicronMapper System with Flex Plan and Unibody Scan Bodies	955-MM1-MSSM-ASY-C
	MicronMapper System with Flex Plan and Split Scan Bodies	955-MM1-MSSM-ASY-D
MicronMapper EVO System 955-MME-ESSM-ASY	MicronMapper EVO System with Unibody Scan Bodies	955-MME-ESSM-ASY-A
	MicronMapper EVO System with Split Scan Bodies	955-MME-ESSM-ASY-B
	MicronMapper EVO System with Split Scan Bodies (1.6 mm)	955-MME-ESSM-ASY-C
MicronMapper Scan Bodies 950-MM1-SCAN-BDY	Series: 00-09 (Set of 10)	950-MM1-SCAN-BDY-0
	Series: 10-19 (Set of 10)	950-MM1-SCAN-BDY-1
	Series: 20-29 (Set of 10)	950-MM1-SCAN-BDY-2
	Series: 30-39 (Set of 10)	950-MM1-SCAN-BDY-3
	Series: 40-49 (Set of 10)	950-MM1-SCAN-BDY-4
MicronMapper Split Scan Bodies 955-MM1-SPLT-BDY	Series: 00-07 (includes 8 Tops + 16 Bases)	955-MM1-SPLT-BDY-0
	Series: 10-17 (includes 8 Tops + 16 Bases)	955-MM1-SPLT-BDY-1
	Series: 20-27 (includes 8 Tops + 16 Bases)	955-MM1-SPLT-BDY-2
	Series: 30-37 (includes 8 Tops + 16 Bases)	955-MM1-SPLT-BDY-3
	Series: 40-47 (includes 8 Tops + 16 Bases)	955-MM1-SPLT-BDY-4
MicronMapper EVO Scan Bodies 950-MME-SCAN-BDY	Series: 70-79 (Set of 10)	950-MME-SCAN-BDY
MicronMapper EVO Split Scan Bodies 955-MME-SPLT-BDY	Series: 70-77 (includes 8 Tops + 16 Bases)	955-MME-SPLT-BDY



MicronMapper Split Scan Bodies (1.6 mm Base) 955-MM1-SS16-BDY	Series: 00-07 (includes 8 Tops + 16 Bases)	955-MM1-SS16-BDY-0
	Series: 10-17 (includes 8 Tops + 16 Bases)	955-MM1-SS16-BDY-1
	Series: 20-27 (includes 8 Tops + 16 Bases)	955-MM1-SS16-BDY-2
	Series: 30-37 (includes 8 Tops + 16 Bases)	955-MM1-SS16-BDY-3
	Series: 40-47 (includes 8 Tops + 16 Bases)	955-MM1-SS16-BDY-4
MicronMapper EVO Split Scan Bodies (1.6 mm) 955-MME-SS16-BDY	Series: 70-77 (includes 8 Tops + 16 Bases)	955-MME-SS16-BDY
MicronMapper Split Scan Bodies (Mini) 955-MM1-SMNI-BDY	Series: 00-07 (includes 8 Tops + 8 Bases)	955-MM1-SMNI-BDY-0
	Series: 10-17 (includes 8 Tops + 8 Bases)	955-MM1-SMNI-BDY-1
	Series: 20-27 (includes 8 Tops + 8 Bases)	955-MM1-SMNI-BDY-2
	Series: 30-37 (includes 8 Tops + 8 Bases)	955-MM1-SMNI-BDY-3
	Series: 40-47 (includes 8 Tops + 8 Bases)	955-MM1-SMNI-BDY-4
MicronMapper Locator Scan Bodies 950-MM1-SLOC-BDY	Series: 40-45 (Set of 6)	950-MM1-SLOC-BDY
MicronMapper Split Scan Body Bases (1.4 mm) 950-MM1-SS14-BSE	Pack of 8	950-MM1-SS14-BSE-8
	Pack of 16	950-MM1-SS14-BSE-16
MicronMapper Split Scan Body Bases (1.6 mm) 950-MM1-SS16-BSE	Pack of 8	950-MM1-SS16-BSE-8
	Pack of 16	950-MM1-SS16-BSE-16
MicronMapper Split Scan Body Bases (Mini) 950-MM1-SMNI-BSE	Pack of 8	950-MM1-SMNI-BSE