



*ClaroNav Inc.*  
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Valid as of January 24, 2018

**Declaration of Conformity**

This declaration is made in accordance with Medical Device Directive 93/42/EEC, Annex II  
as amended by Directive 2007/47/EC

**Name and Address of the Manufacturer:**

ClaroNav Inc.  
1140 Sheppard Ave. West, Unit 10  
Toronto, Ontario, CANADA M3K 2A2

**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:** Navident Model #: 955-ND-ND

**Name and Address of Notified Body:**

Intertek Semko AB  
Torshamnsgatan 43  
Box 1103  
SE-164 22 Kista  
Sweden  
Notified Body Designation: 0413  
Certificate Number (issued by Intertek): 41371373

**Compliance with Annex II of the Medical Device Directive, Council Directive 93/42/EEC as amended by Directive 2007/47/EC**

**Classification of the device:**

Navident is classified as class IIa as per Rule 5, Annex IX

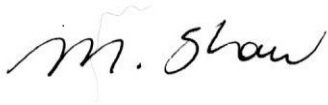
According to rule 5 of Annex IX to Directive 93/42/EEC, all invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or higher active devices intended for diagnosis are in Class IIa. Navident connects to a drill (Class IIa per rule 9).

ClaroNav Inc. declares that Navident bears the CE mark of conformity and complies with the requirement of the Swedish National Board of Health and Welfare Regulation and guidelines on medical devices LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC.

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 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: Michaela Shaw

Title: Director QA/RA

Date: January 24, 2018

### **Appendix A- Navident Product List**

This product list specifies the Class IIa Navident products bearing the Semko CE Mark distributed by ClaroNav Inc. in accordance to the EU Medical Device Directive:

<b>Product Model</b>	<b>REF</b>	<b>Initial Serial/Lot Number</b>
Navident Device	955-ND-ND	101101

The following Class I accessories to the Navident System, are not included in the CE Mark certification, however ClaroNav declares that they are designed and manufactured according to the EU Medical Device Directive:

Navident Procedure Kit	955-ND-PRK	PK2014120114
Navident Accessory Kit	955-ND-ACCK	Not applicable
Navident Training Kit	955-ND-NVTK	Not applicable