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## **EC Declaration of Conformity**

Name of Products: CORGRIP\* Nasogastric/Nasointestinal Feeding Tube

Retention System

Product Codes: See Attachment A

UMDNS Code: 17514 (Nasogastric Tube Holders)

GMDN Code: 62581 (Nasogastric tube holder, intranasal)

Legal Manufacturer (Place of Issue): Avanos Medical, Inc

5405 Windward Parkway

Alpharetta, Georgia (GA) 30004, USA

EU Authorized Representative: Avanos Medical Belgium BVBA

Leonardo Da Vincilaan 1

1930 Zaventem

Belgium

Product Standards: N/A

**Start of CE:** 07/10/2019

Conformity Assessment Route: Annex II

Device Classification, Rules: Class IIa, Rule 5 of Annex IX

CE certificate number: CE 711145

Notified Body: BSI Netherlands (2797)

Quality System Certificate: FM 702907

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

All supporting documentation that contains proof of compliance to the aforementioned Directive(s) is retained under the premises of Avanos Medical, Inc. This declaration applies to all devices on the attached product list from the signature date forward

**Authorized Signature:** 

Name Thomas Kozma

Title Director, Regulatory Affairs

Avanos Medical, Inc.

Date 10 July 2019

## **Attachment A (Product List)**

This attachment specifies the products included in the above referenced Declaration of Conformity

<b>Product Code</b>	Product Description	Sterilization
25-008	CORGRIP* NG/NI Feeding Tube Retention System	Non-Sterile
25-010	CORGRIP* NG/NI Feeding Tube Retention System	Non-Sterile
25-012	CORGRIP* NG/NI Feeding Tube Retention System	Non-Sterile
	CORGRIP* NG/NI Feeding Tube Retention System, For Use with Salem Sump™ Tubes	Non-Sterile
	CORGRIP* NG/NI Feeding Tube Retention System, For Use with Salem Sump™ Tubes	Non-Sterile
	CORGRIP* NG/NI Feeding Tube Retention System, For Use with Salem Sump™ Tubes	Non-Sterile