

EC Declaration of Conformity

Name of Products: Oral Care Products

Product Codes: See **Attachment A**

UMDNS Code: 16619 (Swabs, Oral Care)

GMDN Code: 45172 (Oral care kit, single-use)
10749 (Tracheal suction catheter)

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

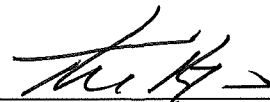
Notified Body: BSI Netherlands (2797)

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

Product Code	Product Description	Sterilization
122	Connection Tubing with Suction Valve with BALLARD* Technology	Non-Sterile
123	Ready Care* Oral Care Suction Probes with BALLARD* Technology	Non-Sterile
1221	Oral Care Suction Catheter for Neonates/Pediatrics with BALLARD* Technology, 6F	Non-Sterile
1222	Oral Care Suction Catheter for Neonates/Pediatrics with BALLARD Technology, 8F	Non-Sterile
1223	Oral Care Suction Catheter for Neonates/Pediatrics with BALLARD Technology, 10F	Non-Sterile
12601	Oral Care Suction Catheter for Adults	Non-Sterile
12602	Oral Care Suction Toothbrush	Non-Sterile
12603	Oral Care Suction Swab	Non-Sterile
12604	Oral Care Suction Tip Yankauer	Non-Sterile
12606	Suction Valve and Y-Adapter	Non-Sterile
12607	Oral Care Suction Swab with Dentifrice	Non-Sterile
99785	Yankauer	Non-Sterile
99786	Suction Handle	Non-Sterile
99789	Oral Care Prep Pack	Non-Sterile
99946	24-Hour Oral Care Kit	Non-Sterile
25928	Oral Care Advanced Kit	Non-Sterile
25929	Oral Care Initial Kit	Non-Sterile
25930	Oral Care Moderate Kit	Non-Sterile
970008-5	Min Oral Care Advanced Kit, CE	Non-Sterile