

## EU Declaration of Conformity

**Legal Manufacturer:**



AVANOS Medical, Inc.  
 5405 Windward Parkway  
 Alpharetta, GA 30004  
 United States of America

**Authorised Representative:**



Avanos Medical Belgium BVBA  
 Leonardo Da Vincilaan 1  
 1930 Zaventem  
 Belgium  
 Single Registration Number (SRN): BE-AR-000002191

**Identification of the device(s):**

**Product Trade Name(s):** BALLARD\* ORAL CARE DENTASWAB WITHOUT DENTIFRICE  
**Basic UDI-DI:** 0609038DENT04801MB

**Product Code(s)/Catalogue Numbers**

**Product Family**

Code	Name and spec of product
12240	BALLARD* Oral Care Swab, Individually Wrapped (Individual swabs pouch wrapped in a 250 units dispenser and packaged in case of 4 dispensers)
12241	BALLARD * Oral Care Swab, Bulk Packed (2 bags of 500 swabs packaged in a case)
12243	BALLARD * Oral Care Swab, Bulk Packed (25 pouches of 20 swabs, wrapped in a dispenser of 25 pouches and packaged in case of 2 dispensers)
12251	BALLARD * Oral Care Swab, Bulk Packed (25 pouches of 20 swabs, wrapped in a dispenser of 25 pouches and packaged in case of 2 dispensers)
12252	BALLARD * Oral Care Swab, Bulk Packed (2 bags of 500 swabs packaged in a case)
12254	BALLARD * Oral Care Swab, Individually Wrapped with Plastic Handle (Individual swabs pouch wrapped in a 250 units dispenser and packaged in case of 4 dispensers)
122548	BALLARD * mini Oral Care Swab, Individually Wrapped with 12 cm Plastic Handle (Individual swabs pouch wrapped in a 250 units dispenser and packaged in case of 4 dispensers)

**Intended Purpose:** *BALLARD\* Oral Care Dentaswab Without Dentifrice is intended to apply mouth moisturizer to the lips and mouth and to wipe teeth and soft tissue in the mouth of patients who require oral hygiene assistance.*

**Risk Class:** *Class 1 ( non-sterile, non-measuring) per Rule 5*

**Conformity Assessment Procedure:** *Annex IX, conformity assessment based on a Quality Management System and on Assessment of Technical Documentation*

**Notified Body:** BSI Group The Netherlands B.V.  
Notified Body Identification Number: 2797

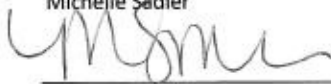
**EU Certificate(s) issued:** *Not Applicable – Class 1 Self-declared*

This EU Declaration of Conformity is issued under the sole responsibility of AVANOS Medical, Inc. The device(s) contained within this declaration are in conformance with EU 2017/745 Medical Device Regulations.

**Identification of the person authorized to sign for and on behalf of Avanos Medical, Inc.:**

Function: Senior Director, Regulatory Affairs

Name: Michelle Sädler

Signature: 

Date: 29-APR-2021

(DD-MMM-YYYY)

Place of Issue: AVANOS Medical - 5405 Windward Parkway Alpharetta, GA 30004  
USA