

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

Identification of the device(s):

Product Code(s)	Trade Name and Description	Product Family	Risk Class	Classification Rule	Start Date of EU MDD/IVDD CE Mark
4616024-01	B.Braun Oral/Enteral Syringe, 1 ml, ENFit®	B. Braun Oral/Enteral Syringes with ENFit® Connector	Ila	Annex IX Rule II	11-May-2016
4616025-01	B.Braun Oral/Enteral Syringe, 2.5 ml, ENFit®	B. Braun Oral/Enteral Syringes with ENFit® Connector	Ila	Annex IX Rule II	11-May-2016
4616026-01	B.Braun Oral/Enteral Syringe, 5ml, ENFit®	B. Braun Oral/Enteral Syringes with ENFit® Connector	Ila	Annex IX Rule II	11-May-2016
4616027-01	B.Braun Oral/Enteral Syringe, 10 ml, ENFit®	B. Braun Oral/Enteral Syringes with ENFit® Connector	Ila	Annex IX Rule II	07-April-2016
4616028-01	B.Braun Oral/Enteral Syringe, 20 ml, ENFit®	B. Braun Oral/Enteral Syringes with ENFit® Connector	Ila	Annex IX Rule II	07-April-2016
4616029-01	B.Braun Oral/Enteral Syringe, 60 ml, ENFit®	B. Braun Oral/Enteral Syringes with ENFit® Connector	Ila	Annex IX Rule II	07-April-2016

Intended Use: The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

Conformity Assessment Procedure: Annex II

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

EU Certificate(s) issued: CE 711145 (Full CE Certificate). The products covered by this DoC have a valid EC certificate that was issued in accordance with Directive 93/42/EEC prior to May 26 2021, and benefit from the transitional provisions in art 120 of Regulation EU 2017/745.

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 Medical Device Directive (MDD): 93/42/EEC and/or In Vitro Diagnostic Directive (IVDD): 98/79/E.

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

Signature: _____

Name: Nikin Desai

Title: (Associate Director, Global Regulatory Affairs)

Date: 18 March 2022
(DD-MMM-YYYY)

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