

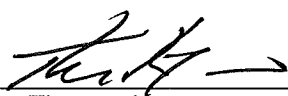
EC Declaration of Conformity

Name of Products:	Enteral Feeding Accessories
Product Codes:	See Attachment A
UMDNS Code:	11677 (Enteral Feeding Kits) 16825 (Syringe Tip Cap)
GMDN Code:	35419 (Gastrostomy tube) 16825 (Syringe Tip Cap)
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:	BS EN 1615 2000 BS EN 1618 1997 BS EN ISO 80369-1 2010 (ENFit connectors only) BS EN ISO 80369-3 2016 (ENFit connectors only) BS EN ISO 80369-20 2015 (ENFit connectors only)
Start of CE:	See Attachment A
Conformity Assessment Route:	Annex II
Device Classification, Rules:	Class IIa, Rule 2 or 6 of Annex IX (See Attachment A)
CE certificate number:	CE 711145
Notified Body:	BSI Netherlands (2797)
ISO 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	Classification Rule	Start Date of CE
0105-06	MIC* Extension Tubing with Bolus and Stepped Connectors at Opposite Ends	Two	07/10/2019
0105-12	MIC* Extension Tubing with Bolus and Stepped Connectors at Opposite Ends	Two	07/10/2019
0106-12	MIC* Extension Tubing with Threaded Feeding Port and Stepped Connector at Opposite Ends, 12"	Two	07/10/2019
0121-12	MIC-KEY* Continuous Feed Extension Set with Secur-Lok* Right	Two	07/10/2019
0121-24	MIC-KEY* Continuous Feed Extension Set with Secur-Lok* Right Angle Connector and 2 Port "Y" and Clamp, 24"	Two	07/10/2019
0122-02	MIC-KEY* Medication Extension Set with Secur-Lok* Right Angle Connector and 2 Port "Y", 2"	Two	07/10/2019
0123-12	MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK* Straight Connector and Clamp, 12"	Two	07/10/2019
0123-24	MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK* Straight Connector and Clamp, 24"	Two	07/10/2019
0124-12	MIC-KEY* Extension Set with Cath Tip, SECUR-LOK* Right Angle Connector and Clamp, 12"	Two	07/10/2019
0124-24	MIC-KEY* Extension Set with Cath Tip, SECUR-LOK* Right Angle Connector and Clamp, 24"	Two	07/10/2019
0126-12	MIC-KEY* Threaded Extension Set with Secur-Lok* Right Angle Connector and Clamp, 12"	Two	07/10/2019
0126-24	MIC-KEY* Threaded Extension Set with Secur-Lok* Right Angle Connector and Clamp, 24"	Two	07/10/2019
0321-12	MIC-KEY* Continuous Extension Set with Secur-Lok* Right Angle Connector and Male Luer Medication Port, 12"	Two	07/10/2019
0321-24	MIC-KEY* Continuous Extension Set with Secur-Lok* Right Angle Connector and Male Luer Medication Port, 24"	Two	07/10/2019

98702	Enteral Access Dilation System, 16 Fr	Six	07/10/2019
98703	Enteral Access Dilation System, 18 Fr	Six	07/10/2019
98704	Enteral Access Dilation System, 20 Fr	Six	07/10/2019
98705	Enteral Access Dilation System, 22 Fr	Six	07/10/2019
98706	Enteral Access Dilation System, 24 Fr	Six	07/10/2019
0142-02	MIC-KEY* Medication Extension Set with ENFit™ Connectors, SECUR-LOK* Right Angle Connector, 2 Port "Y" ENFit™ Connectors, 5 cm, 2"	Two	07/10/2019
0141-12	MIC-KEY* Continuous Feed Extension Set with ENFit™ Connectors, SECUR-LOK* Right Angle Connector, 2 Port "Y" ENFit™ Connectors and Clamp, 30 cm, 12"	Two	07/10/2019
0141-24	MIC-KEY* Continuous Feed Extension Set with ENFit™ Connectors, SECUR-LOK* Right Angle Connector, 2 Port "Y" ENFit™ Connectors and Clamp, 60 cm, 24"	Two	07/10/2019
0143-12	MIC-KEY* Bolus Feed Extension Set with ENFit™ Connector, SECUR-LOK* Straight Connector, Bolus ENFit™ Connector and Clamp, 30 cm, 12"	Two	07/10/2019
0143-24	MIC-KEY* Bolus Feed Extension Set with ENFit™ Connector, SECUR-LOK* Straight Connector, Bolus ENFit™ Connector and Clamp, 60 cm, 24"	Two	07/10/2019
0144-12	MIC-KEY* Single Port Feed Extension Set with ENFit® Connector, SECUR-LOK* Right Angle Connector and Bolus ENFit® Connector and Clamp	Two	07/10/2019
0144-24	MIC-KEY* Single Port Feed Extension Set with ENFit® Connector, SECUR-LOK* Right Angle Connector and Bolus ENFit® Connector and Clamp	Two	07/10/2019
0141-12-200	MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors, SECUR-LOK* Right Angle Connector, 2 Port "Y" ENFit® Connectors and Clamp, 30 cm	Two	07/10/2019
0141-24-200	MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors, SECUR-LOK* Right Angle Connector, 2 Port "Y" ENFit® Connectors and Clamp, 60 cm	Two	07/10/2019
0143-12-200	MIC-KEY* Bolus Feed Extension Set with ENFit® Connector, SECUR-LOK* Straight Connector, Bolus ENFit® Connector and Clamp, 30 cm	Two	07/10/2019
0143-24-200	MIC-KEY* Bolus Feed Extension Set with ENFit® Connector, SECUR-LOK* Straight Connector, Bolus ENFit® Connector and Clamp, 60 cm	Two	07/10/2019
0144-12-200	MIC-KEY* Single Port Feed Extension Set with ENFit® Connector, SECUR-LOK* Right Angle Connector and Bolus ENFit® Connector and Clamp, 30 cm	Two	07/10/2019
0144-24-200	MIC-KEY* Single Port Feed Extension Set with ENFit® Connector, SECUR-LOK* Right Angle Connector and Bolus ENFit® Connector and Clamp, 60 cm	Two	07/10/2019
7121-02	MIC-KEY* SF Continuous Feed Extension Set, 5pk, 2 in	Two	07/10/2019
7121-12	MIC-KEY* SF Continuous Feed Extension Set, 5pk, 12 in	Two	07/10/2019
7121-24	MIC-KEY* SF Continuous Feed Extension Set, 5pk, 24 in	Two	07/10/2019
7123-02	MIC-KEY* SF Bolus Feed Extension Set, 5pk, 2 in	Two	07/10/2019
7123-12	MIC-KEY* SF Bolus Feed Extension Set, 5pk, 12 in	Two	07/10/2019
7123-24	MIC-KEY* SF Bolus Feed Extension Set, 5pk, 24 in	Two	07/10/2019
7128-00	MIC-KEY* SF Patient Starter Kit	Two	07/10/2019
7141-02	MIC-KEY* SF Continuous Feed Extension Set with ENFit® Connectors, 2 in	Two	07/10/2019
7141-12	MIC-KEY* SF Continuous Feed Extension Set with ENFit® Connectors, 12 in	Two	07/10/2019
7141-24	MIC-KEY* SF Continuous Feed Extension Set with ENFit® Connectors, 24 in	Two	07/10/2019
7143-02	MIC-KEY* SF Bolus Feed Extension Set with ENFit® Connectors, 2 in	Two	07/10/2019
7143-12	MIC-KEY* SF Bolus Feed Extension Set with ENFit® Connectors, 12 in	Two	07/10/2019
7143-24	MIC-KEY* SF Bolus Feed Extension Set with ENFit® Connectors, 24 in	Two	07/10/2019

7148-00	MIC-KEY* SF Patient Starter Kits, Extension Sets with ENFit® Connectors, Secure Flow Technology	Two	07/10/2019
SRC-01NS	Self-Righting Cap with ENFit Compatible Connector	One	07/10/2019