

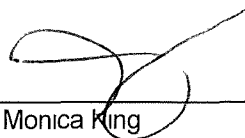
EC Declaration of Conformity

Name of Products:	Gastric - Jejunal Feeding Tubes
Product Codes:	See Attachment A
UMDNS Code:	11677 (Enteral Feeding Kits)
GMDN Code:	38564 (Jejunostomy tube)
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 (full compliance for all codes with exception of the four codes below) BS EN 1615 2000 (with the exception of section 4.2.2) 0210-16, 0210-16LV, 0210-18, 0210-18LV BS EN ISO 80369-3 2016 (ENFit codes only)
Start of CE:	See Attachment A
Conformity Assessment Route:	Annex II
Device Classification, Rules:	Class IIb, Rule 5 and 8 of Annex IX
CE certificate number:	CE 711145
Notified Body:	BSI Netherlands (2797)
Quality Management 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	Monica King
Title	Associate Director, Regulatory Affairs Avanos Medical, Inc
Date	21 October 2019

Attachment A (Product List)

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

Product Code	Product Description	Start of CE Mark
0210-16	MIC* Gastro-Enteric Feeding Tube, 16Fr / 7-10ml	07/10/2019
0210-16LV	MIC* Gastro-Enteric Feeding Tube, 16Fr / 3-5ml	07/10/2019
0210-18	MIC* Gastro-Enteric Feeding Tube, 18Fr / 7-10ml	07/10/2019
0210-18LV	MIC* Gastro-Enteric Feeding Tube, 18Fr / 3-5ml	07/10/2019
0210-20	MIC* Gastro-Enteric Feeding Tube, 20Fr / 7-10ml	07/10/2019
0210-22	MIC* Gastro-Enteric Feeding Tube, 22Fr / 7-10ml	07/10/2019
0210-24	MIC* Gastro-Enteric Feeding Tube, 24Fr / 7-10ml	07/10/2019
0210-26	MIC* Gastro-Enteric Feeding Tube, 26Fr / 7-10ml	07/10/2019
0210-28	MIC* Gastro-Enteric Feeding Tube, 28Fr / 7-10ml	07/10/2019
0210-30	MIC* Gastro-Enteric Feeding Tube, 30Fr / 7-10ml	07/10/2019
0270-14-4 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-14-4 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-14-5 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-14-5 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-14-6 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-14-6 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-14-7 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 14Fr / 45cm	07/10/2019
0270-16-1 0-15	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 15cm – 3-5ml	07/10/2019
0270-16-1 0-22	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 22cm – 3-5ml	07/10/2019
0270-16-1 2-15	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 15cm – 3-5ml	07/10/2019
0270-16-1 2-22	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 22cm – 3-5ml	07/10/2019
0270-16-1 2-30	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 30cm – 3-5ml	07/10/2019
0270-16-1 5-15	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 15cm – 3-5ml	07/10/2019
0270-16-1 5-22	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 22cm – 3-5ml	07/10/2019
0270-16-1 5-30	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 30cm – 3-5ml	07/10/2019
0270-16-1 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 45cm – 7-10ml	07/10/2019
0270-16-1 7-15	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 15cm – 3-5ml	07/10/2019
0270-16-1 7-22	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 22cm – 3-5ml	07/10/2019
0270-16-1 7-30	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 30cm – 3-5ml	07/10/2019
0270-16-1 7-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 16Fr / 45cm – 7-10ml	07/10/2019

Product Code	Product Description	Start of CE Mark
0270-18-2 7-30	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 30cm – 3-5ml	07/10/2019
0270-18-2 7-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm – 7-10ml	07/10/2019
0270-18-3 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm – 7-10ml	07/10/2019
0270-18-3 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm – 7-10ml	07/10/2019
0270-18-4 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-18-4 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-18-5 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-18-5 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-18-6 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-18-6 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-18-7 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 18Fr / 45cm	07/10/2019
0270-22-1 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-1 7-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-2 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-2 3-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-2 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-2 7-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-3 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-3 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm – 7-10ml	07/10/2019
0270-22-4 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
0270-22-4 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
0270-22-5 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
0270-22-5 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
0270-22-6 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
0270-22-6 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
0270-22-7 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit, Low-Profile (Endoscopic / Radiologic Placement), 22Fr / 45cm	07/10/2019
8210-16	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 16Fr/ 7-10ml/ 57 9cm	07/10/2019
8210-16LV	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 16Fr/ 3-5ml/ 25 4cm	07/10/2019
8210-18	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 18Fr/ 7-10ml/ 57 9cm	07/10/2019
8210-18LV	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 18Fr/ 3-5ml/ 25 4cm	07/10/2019
8210-20	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 20Fr/ 7-10ml/ 57 9cm	07/10/2019
8210-22	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 22Fr/ 7-10ml/ 57 9cm	07/10/2019
8210-24	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 24Fr/ 7-10ml/ 57 9cm	07/10/2019
8210-26	MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors, 26Fr/ 7-10ml/ 57 9cm	07/10/2019

Product Code	Product Description	Start of CE Mark
8270-22-6 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit Extension Sets with ENFit* Connectors	07/10/2019
8270-22-6 5-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit Extension Sets with ENFit* Connectors	07/10/2019
8270-22-7 0-45	MIC-KEY* Gastric-Jejunal Feeding Tube Kit Extension Sets with ENFit* Connectors	07/10/2019
0650-16	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 16Fr / 45cm	07/10/2019
0650-16-15	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 16Fr / 15cm	07/10/2019
0650-16-22	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 16Fr / 22cm	07/10/2019
0650-16-30	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 16Fr / 30cm	07/10/2019
0650-18	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 18Fr / 45cm	07/10/2019
0650-18-22	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 18Fr / 22cm	07/10/2019
0650-18-30	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 18Fr / 30cm	07/10/2019
0650-22	MIC* Gastric-Jejunal Feeding Tube Kit, (Endoscopic/Radiologic Placement) 22Fr / 45cm	07/10/2019
0660-16	MIC* Gastric-Jejunal Feeding Tube (Surgical Placement), 16Fr / 45cm	07/10/2019
0660-18	MIC* Gastric-Jejunal Feeding Tube (Surgical Placement), 18Fr / 45cm	07/10/2019
0660-22	MIC* Gastric-Jejunal Feeding Tube (Surgical Placement), 22Fr / 45cm	07/10/2019
8650-16	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 16 Fr/45cm	07/10/2019
8650-16-15	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 16 Fr/15cm	07/10/2019
8650-16-22	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 16 Fr/22cm	07/10/2019
8650-16-30	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 16 Fr/30cm	07/10/2019
8650-18	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 18 Fr/45cm	07/10/2019
8650-18-22	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 18 Fr/22cm	07/10/2019
8650-18-30	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 18 Fr/30cm	07/10/2019
8650-22	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Endoscopic/Radiologic Placement Kit), 22 Fr/45cm	07/10/2019
8660-16	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Surgical Placement Kit)	07/10/2019
8660-18	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Surgical Placement Kit)	07/10/2019
8660-22	MIC* Gastric-Jejunal Feeding Tube with ENFit® Connectors (Surgical Placement Kit)	07/10/2019