

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 711145****Issued To:**

**Avanos Medical Inc.
5405 Windward Parkway
Alpharetta
Georgia
30004
USA**

In respect of:

The design, development, and manufacture of enteral feeding devices, access devices, closed tracheal and oral suction systems, non-active endoscopy devices and accessories, sterile non-active respiratory devices, digestive tract devices, endotracheal tubes, gastrointestinal anchor sets, cannulas/introducers for use in RF pain management systems, sterile, single use enteral feeding tubes, enteral extension sets, sterile and non-sterile single use oral/enteral syringes and non-sterile, reusable oral/enteral syringes.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-07-10**

Date: **2021-04-14**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 711145

Issued To:

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5405 Windward Parkway
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Georgia
30004
USA

NBOG code(s)	Device Description	Intended purpose per IFU
Class III		
MD0204	Enteral feeding introducer kits	As per CE 711371.
MDS7006	Gastrointestinal anchor sets	
SMD7009		
Class IIb		
MD0102	Enteral feeding and access devices	To deliver food or medications directly in to the stomach, duodenum or jejunum
MDS7006		
Class IIa		
MD0101	Closed suction system & accessories	N/A for class IIa
MDS7006		
MD0102	MAC catheter	
MDS7006	Enteral feeding accessories: extension sets, PEG accessories, dilation systems	
	Paracentesis tray, kit and needles	
	BAL catheter	
	Cuffed endotracheal tubes	

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NBOG code(s)	Device Description	Intended purpose per IFU
Class IIa		
MD0106 MDS7006	Endoscopy grasping & retrieving devices, polypectomy snares, biopsy forceps, baskets and graspers	N/A for class IIa
	Sterile introducers & cannulas for use in RF pain management systems	
	Injection needle catheters	
MD0401 MDS7006	Oral care system & accessories	
MD0102 MDS7006	Legacy Oral/Enteral Syringes and Dispenser (with Enteral Only Connectors)	
	Oral/Enteral Syringes with ENFit Connectors	
	Legacy Enteral Feeding Tubes & Extension Sets (with Enteral Only Connectors)	
	Enteral Feeding Tubes & Extension Sets with ENFit Connectors	
	Legacy and ENFit Sampling Straws	

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NBOG code(s)	Device Description	Intended purpose per IFU
Class IIa		
MD0102	Legacy Oral/Enteral Syringes and Dispenser (with Enteral Only Connectors)	N/A for class IIa
	Oral/Enteral Syringes with ENFit Connectors (single-use)	
	Oral/Enteral Syringes with ENFit Connectors (reusable)	

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