

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:

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

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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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List of Significant Subcontractors

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Subcontractor:	Service(s) supplied
Anhui Tiankang Medical Technology Co., Ltd. No. 228 Wiyi Road Economic Development Zone Tianchang City 239300 Anhui China	ETO Sterilization Manufacture
Avanos Medical Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium	EU Representative
Avent Inc 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	Manufacture

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Subcontractor:	Service(s) supplied
Avent S. de R. L. de C.V. Privada Baja California B-2 Int B Fraccionamiento Rubio Tijuana Baja California 22116 Mexico	Manufacture
Avent S. de R.L. de C.V. Circuito Industrial No. 40 Colonia Obrera Nogales CP 84048 Mexico	Manufacture
Avent S. de R.L. de C.V. Nogales II Avenida El Castillo # 17-B Nogales CP 84094 Mexico	Manufacture

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Avent S. de R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena Sonora CP 84160 Mexico	Manufacture
Avent S. de R.L. de C.V. Privada Baja California Edificio B2 Fraccionamiento Rubio Tijuana Baja California 22116 Mexico	Manufacture
Avent S. de R.L. de C.V. Ave Noruega Edificio D-1B Fraccionamiento, Rubio Tijuana B.C. 22116 Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Centurion Medical Products Corporation 301 Catrell Drive Howell Michigan 48843 USA	ETO Sterilization
Centurion Medical Products Corporation 3173 East 43rd Street Yuma Arizona 85365 USA	ETO Sterilization
Command Medical Nicaragua SA Km 12.5 Carretera Norte Parque Industrial Las Mercedes Edificio 16 Managua Nicaragua	Manufacture

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Subcontractor:	Service(s) supplied
Cosmed Group Inc. 2205 East 33rd Street Erie Pennsylvania 16510 USA	ETO Sterilization
Fortune Medical Instrument Corp. 6F., No. 29, Sec. 2, Jhongjheng E. Rd. Danshuei Dist New Taipei City 251 Taiwan	Manufacture
Isomedix Operations, Inc 1000 South Sarah Place Ontario California 91761 USA	Radiation (Gamma Sterilization)

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Subcontractor:

Service(s) supplied

Isomedix Operations, Inc.
1435 Isomedix Place
El Paso
Texas
79936
USA

**ETO Sterilization
Radiation (Gamma Sterilization)**

Isomedix Operations, Inc.
43425 Business Park Drive
Temecula
California
92590
USA

ETO Sterilization

Isomedix Operations, Inc.
9120 South 150 East
Sandy
Utah
84070
USA

Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	ETO Sterilization
Martech Medical Products, Inc. 1500 Delp Drive Harleysville PA 19438 USA	Manufacture
Medical Murray Incorporated 540 Capital Drive, Suite 150 Lake Zurich Illinois 60047 USA	Manufacture

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Subcontractor:	Service(s) supplied
Ningbo Tianyi Medical Appliance Co., Ltd. No. 788, Mozhi North Road Tourism Resort, Dongqian Lake 315121 Ningbo People's Republic of China	ETO Sterilization Manufacture
Northpoint Services Division 1160 S. Northpoint Blvd Waukegan Illinois 60085 USA	ETO Sterilization
Pro-Tech Design & Manufacturing, Inc. 14561 Marquardt Avenue Santa Fe Springs CA 90670 USA	ETO Sterilization Manufacture

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Subcontractor:	Service(s) supplied
SEI MEDICAL S.A. DE C.V. (SEISA MEDICAL INC) Roberto Fierro #6420 & Francisco Sarabia Parque Industrial Aeropuerto 32695 Ciudad Juarez Chihuahua Mexico	Manufacture
Sterigenics US LLC 344 Bonnie Circle Corona California 92880 USA	Radiation (Gamma Sterilization)
Sterigenics US LLC 3125 Wichita Court Fort Worth Texas 76140 USA	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
Trident Manufacturing, Inc. 14N002 Prairie Street Pingree Grove Illinois 60140-0140 USA	Manufacture
Vitaltec Corporation No.12, Lane 4-30, Chyuan-Zhou Rd. Hou-Li Dist. 42142 Taichung City Taiwan	ETO Sterilization Manufacture

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Date	Reference Number	Action
10 July 2019	9770894	First issue. Mirror certificate of CE 621870.
15 May 2020	3068918	Renewal Addition of critical subcontractor Cosmed Group Inc Change to services supplied by Avent Inc – Irvine: removal of administration & complaints and addition of design Addition of Inc to Martech Medical Products name Change to name and zip code of Trident Manufacturing Inc. Change to device NBOG codes in supplementary table
31 December 2020	3283288	Remove: "and sterile Anesthesia Conduction Needles and Kits", from scope. Remove "anesthesia conduction needles & kits" from device table. Remove subcontractor Avent, Inc. 43 Discovery, Suite 100 Irvine California 92618 USA.

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Current	3373949	Addition of "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" to certificate scope; addition of enteral feeding devices and accessories to supplementary device table; Addition of the following critical subcontractors: Fortune Medical Instrument Corp., Vitaltec Corporation, Pro-Tech Design & Manufacturing, Inc., Anhui Tiangkang Medical Technology Co., Ltd., Ningbo Tianyi Medical Appliance Co., Ltd., Avent S. de R.L.de C.V (Building B-2 Int B).