By Royal Charter

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 and sterile Anesthesia Conduction Needles and Kits

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: **2020-05-15** 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.

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.
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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 MDS7006 SMD7009	Enteral feeding introducer kits	As per CE 711371.
	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	Not applicable for class IIa devices
MD0102 MDS7006	MAC catheter	
	Enteral feeding accessories: extension sets, PEG accessories, dilation systems	
	Paracentesis tray, kit and needles	
	BAL catheter	
	Cuffed endotracheal tubes	
	Anaesthesia conduction needles & kits	

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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	Not applicable for class IIa devices
	Sterile introducers & cannulas for use in RF pain management systems	
	Injection needle catheters	
MD0401 MDS7006	Oral care system & accessories	

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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

Subcontractor:	**Service(s) supplied**
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**
Avent S. de R.L. de C.V. Circuito Industrial No. 40 Colonia Obrera Nogales CP 84048 Mexico	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Avent S. de R.L. de C.V. Nogales II Avenida El Castillo # 17-B Nogales CP 84094 Mexico	**Manufacture**
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**

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Subcontractor:	**Service(s) supplied**
Avent S. de R.L. de C.V. Ave Noruega Edificio D-1B Fraccionamiento, Rubio Tijuana B.C. 22116 Mexico	**Manufacture**
Avent, Inc 43 Discovery, Suite 100 Irvine California 92618 USA	**Design**
Centurion Medical Products Corporation 301 Catrell Drive Howell Michigan 48843 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
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**
Cosmed Group Inc. 2205 East 33rd Street Erie Pennsylvania 16510 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc 1000 South Sarah Place Ontario California 91761 USA	**Radiation (Gamma Sterilization)**
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**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	**Radiation (Gamma Sterilization)**
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**

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Subcontractor:	**Service(s) supplied**
Medical Murray Incorporated 540 Capital Drive, Suite 150 Lake Zurich Illinois 60047 USA	**Manufacture**
Northpoint Services Division 1160 S. Northpoint Blvd Waukegan Illinois 60085 USA	**ETO Sterilization**
SEI MEDICAL S.A. DE C.V. (SEISA MEDICAL INC) Roberto Fierro #6420 & Francisco Sarabia Parque Industrial Aeropuerto 32695 Ciudad Juarez Chihuahua Mexico	**Manufacture**

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Subcontractor:	**Service(s) supplied**
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)**
Trident Manufacturing, Inc. 14N002 Prairie Street Pingree Grove Illinois 60140-0140 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
10 July 2019	9770894	First issue. Mirror certificate of CE 621870.
Current	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

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