

EC Certificate - Full Quality Assurance System

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

No. CE 621870
Issued To: Halyard Health, 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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 March 2015**

Date: **02 March 2016**

Expiry Date: **13 February 2021**

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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 621870

Issued To:

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This certificate covers the following products:

Enteral Feeding Devices Gamma Sterilized
Enteral Feeding Devices EtO Sterilized i.e. 12F MIC-Key, PEG
Enteral Feeding Accessories i.e. Extension Sets, PEG Accessories, Dilation Systems
Introducer Kits
Closed Suction System and Accessories
Oral Care System and Accessories
MAC Cath
Polypectomy Snare
Thermal Option Biopsy Forceps
Injection Needle Catheters
Paracentesis Tray, Kit and Needles
BAL Cath
Retrieval Devices i.e. Baskets, Graspers
Cuffed Endotracheal Tubes
Gastrointestinal Anchor Sets
Cannulas/Introducers for use in RF Pain Management Systems
Sterile Anesthesia Conduction Needles and Kits

First Issued: **23 March 2015**Date: **02 March 2016**Expiry Date: **13 February 2021**

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Avent Inc - ATW 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	Manufacture
Avent R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena Sonora CP 84160 Mexico	Manufacture
Avent S de R.L. de C.V. Circuito Industrial No. 40 Colonia Obrera Nogales Sonora CP 84048 Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Avent S. de R.L. de C.V. Avenida del Castillo #17-B Nogales CP 84094 Mexico	Manufacture
Baylis Medical Company Inc. 5959 Trans-Canada Highway Montreal Québec H4T 1A1 Canada	Manufacture
Centurion Sterilization Services A Division of Centurion Medical Products Corporation 3173 East 43rd Street Yuma Arizona 85365 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Centurion Sterilization Services A Division of Tri-State Hospital Supply 301 Catrell Drive Howell Michigan 48843 USA	ETO Sterilization
Halyard - Irvine 43 Discovery, Suite 100 Irvine California 92618 USA	Administration & Complaints
Halyard Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium	EU Representative

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Subcontractor:	Service(s) supplied
iuvo BioScience - Erie, LLC 2205 East 33rd Street Erie Pennsylvania 16510 USA	ETO Sterilization
Martech Medical Products 1500 Delp Drive Harleysville Pennsylvania 19438 USA	Manufacture
Sterigenics US, LLC, 3125 Wichita Court Fort Worth, 76140 Texas USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
STERIS Isomedix Services Inc. 9120 South 150 East Sandy Utah 84070 USA	Gamma Sterilization
STERIS Isomedix Services, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	ETO Sterilization Gamma Sterilization

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Subcontractor:	Service(s) supplied
STERIS Isomedix Services 1000 South Sarah Place Ontario California 91761 USA	Gamma Sterilization
STERIS Isomedix Services 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization
Synergy Sterilisation Kulim (M) Sdn Bhd Lot 71, Kulim Industrial Estate 09000 Kulim Kedah Malaysia	ETO Sterilization

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Subcontractor:	Service(s) supplied
Trident Manufacturing Inc. 14N002 Prairie Street Pingree Grove Illinois 60140 USA	Manufacture
Unomedical Snd. Bhd., Bakar Arang Industrial Estate 08000 Sungai Petani Kedah Malaysia	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 621870**
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Date	Reference Number	Action
23 March 2015	8255587	First issue, mirror certificate of CE 556100.
30 November 2015	8411341	Addition of significant subcontractor Sterigenics US, LLC, 3125 Wichita Court, Fort Worth, Texas 76140, USA for Gamma Sterilization. Subcontractor name change from 'MMC Sterilization Services Group, Inc.' to 'iuvo BioScience - Erie, LLC'. Correction of subcontractor address for 'Unomedical Sdn. Bhd.,' to include 'Kedah'. Correction of subcontractor address for 'Avent R.L. de C.V.' (Magdalena) and 'Avent R.L. de C.V.' (Circuito Industrial No, 40, Nogales) to include 'Sonora'. Correction of subcontractor address for 'Trident Manufacturing Inc.' from '14N002 Prairie Grove, Illinois' to '14N002 Prairie Street, Illinois 60140'.
02 March 2016	8472511	Addition of 'Sterile Anesthesia Conduction Needles and Kits' to the product list. Certificate renewal.