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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 621867**

Issued To: **Halyard Health, Inc.**
5405 Windward Parkway
Alpharetta
Georgia
30004
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Certificate No: CE 621867

Certificate Scope:

The manufacture of surgical drapes

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of surgical gowns, drapes and packs, non active respiratory devices and pain management clamps

Those aspects of Annex V related to metrology and securing and maintaining sterility in the manufacture of digestive tract devices and measurement devices for use in RF Pain Management Systems

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

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Supplementary Information to CE 621867

Issued To:

Halyard Health, Inc.
5405 Windward Parkway
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This certificate covers the following product(s):

Surgical Gowns

Surgical Drapes

Surgical Packs

Neonatal Percussor

Enteral Feeding Accessories i.e. Stoma Measuring Device

Cytology

Saline Vials for use with the Trach Care System

Saline Vials for Airway Lavage

Pain Management Clamps

Epsilon Ruler

Analog Manometer

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 621867**
Date:	**02 March 2016**
Issued To:	**Hayard Health, Inc.** **5405 Windward Parkway** **Alpharetta** **Georgia** **30004** **USA**

Subcontractor:	**Service(s) supplied**
Atrion Medical Products, Inc 1426 Curt Francis Road Arab Alabama 35016 USA	**Manufacture**
Avent de Honduras, S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	**Manufacture**
Avent Inc - ATW 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	**Manufacture**

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5405 Windward Parkway
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Subcontractor:	Service(s) supplied
Avent R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena CP 84160 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. AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales CP 84093 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**
GRI Medical & Electronic Technology Technology Co., Ltd. Xiuzhou Industry Zone 1805 Honggao Jiaxing 314031 China	**Manufacture**
Halyard Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium	**EU Representative**

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Subcontractor:	Service(s) supplied
Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiunian Export Processing Zone Lianyungang 22049 China	**Manufacture**
Master & Frank (Pinghu) Co., Ltd. No. 2000, Xingping 2nd Rd. Pinghu Economic Development Zone 310006 Zhejiang China	**Manufacture**
Sterigenics S. de R.L. de C.V. James Watt No 22 Parque Industrial Cuamatla Cuautitlán Izcalli Estado de México 54730 Mexico	**ETO Sterilization**

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Subcontractor:	Service(s) supplied
Sterigenics Shanghai ETO Ltd No. 333, Shuang Hui Road Yang Shan Free Port 201308 Shanghai China	**ETO Sterilization**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics US, LLC 687 Wannamaker Avenue Ontario California 91761 USA	**ETO Sterilization**
Sterigenics, Inc. 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics 2973 Olympic Industrial Drive Smyrna Georgia 30080 USA	**ETO 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 1175 Isuzu Parkway Grand Prairie Texas 75050 USA	**ETO Sterilization**
STERIS Isomedix Services 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 621867**

Date: **02 March 2016**

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Date	Reference Number	Action
23 March 2015	8255587	First issue, mirror certificate of CE 556098
02 March 2016	8472509	Certificate renewal.

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