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By Royal Charter

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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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 621870**

Date: **02 March 2016**

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

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**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" EXIM IDNO 1009600033242 REPUBLICA MOLDOVA

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 621870**

Date: **02 March 2016**

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

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**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "ENDO-CHIRURGIE" IDNO 1009600033242 REPUBLICA MOLDOVA

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 621870**

Date: **02 March 2016**

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

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**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ENDO-CHIRURGIE" S.R.L. IDNO 1008600033242 REPUBLICA MOLDOVA

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 621870**
Date:	**02 March 2016**
Issued To:	**Halyard Health, Inc.** **5405 Windward Parkway** **Alpharetta** **Georgia** **30004** **USA**

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

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No: **FM 697013**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09
Effective Date: 2020-01-09
Latest Revision Date: 2020-01-08
Expiry Date: 2023-01-08

SCC Accredited CB-MS OCSM Accrédité CCN

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Certificate No: **FM 697013**

Location	Registered Activities
La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ENDO-CHIRURGIE" SRL IDNO 1009600033242 REPUBLICA MOLDOVA

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 075182 0006 Rev. 00

Manufacturer:

PULSION Medical Systems SE
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies):

PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

Product Category(ies):

Patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713153619

Valid from: 2019-05-17
Valid until: 2023-05-24

Date, 2019-05-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 075182 0005 Rev. 00

Holder of Certificate: **PULSION Medical Systems SE**
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies): PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, manufacturing, packaging, marketing, sales and servicing of patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713153619

Valid from: 2019-05-17
Valid until: 2021-05-24

I. Preiß

Date, 2019-05-17 Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany