

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:

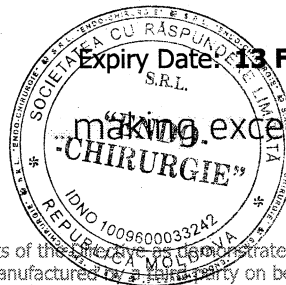
The design, development and manufacture of Enteral Feeding Devices, Access Devices, Closed Tracheal and Oral Suction Systems, Non-Active Endoscopy Devices and Accessories, sterile Non-Active Respiratory Devices, Digestive Tract Devices, Endotracheal Tubes, Gastrointestinal Anchor Sets, Cannulas/Introducers 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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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



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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



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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



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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

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

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.

Gary E Slack, Senior Vice President, Medical Devices

S.R.L.
 "CHIRURGIE"
 Effective Date
 Expiry Date: 2



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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **FM 697013**

Location

Registered Activities

La Ada de Acuna
Kim. 4.5 Carreterra Presa La Amistad
Ciudad De Acuna
Coahuila
26220
Mexico

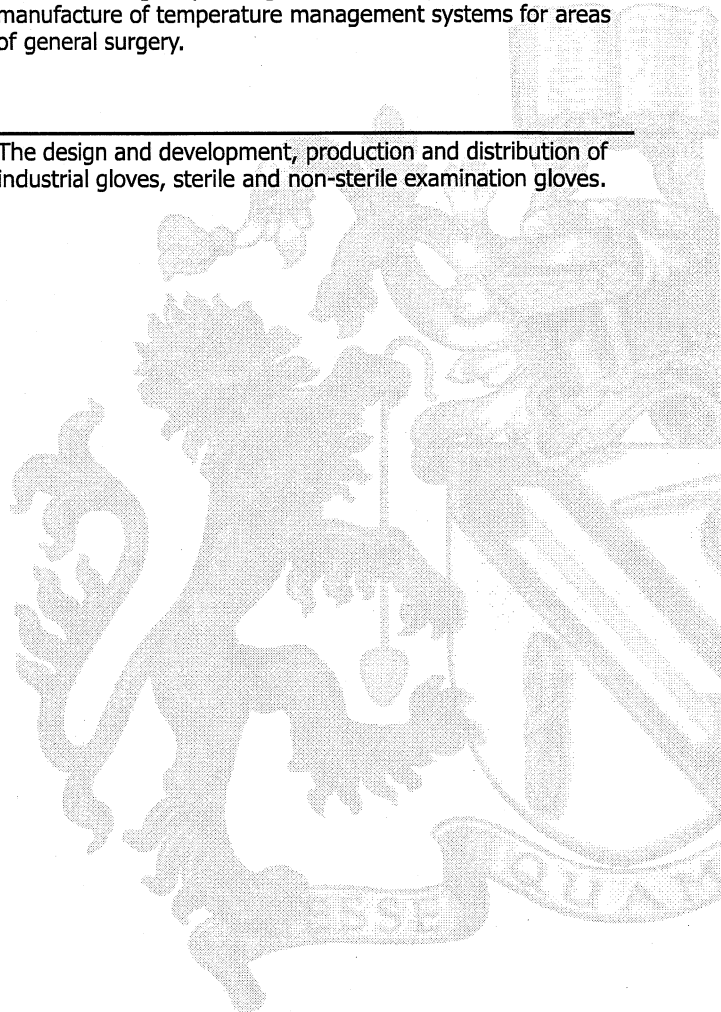
The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.

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

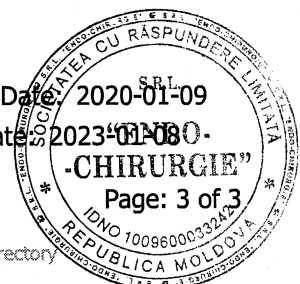
Expiry Date: 2023-01-08

CHIRURGIE

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.





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 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



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

Date, 2019-05-17

Stefan Preiß