

# EC Certificate - Production Quality Assurance

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

**No.****CE 698961****Issued To:**

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

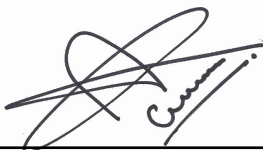
In respect of:

**The manufacture of Surgical Drapes.**

**Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile surgical gowns, surgical drapes, surgical packs and examination gloves**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2019-02-18**

Date: **2019-02-25**

Expiry Date: **2024-02-17**

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Page 1 of 2

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.

# EC Certificate - Production Quality Assurance

## Supplementary Information to CE 698961

Issued To:

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**23116**  
**USA**

Number	Device Name	Intended Purpose per IFU
<b>Class IIa</b>		
MD 0101	Transurethral Resection (T.U.R.) Drapes & Packs	N/A
<b>Class Is</b>		
MDS7006	Surgical Gowns	N/A
MDS7006	Surgical Drapes	N/A
MDS7006	Surgical Packs	N/A
MDS7006	Examination Gloves	N/A

First Issued: **2019-02-18**Date: **2019-02-25**Expiry Date: **2024-02-17**

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Page 2 of 2

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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.

A member of BSI Group of Companies.

# 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 698961**  
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**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
Arc Royal Virginia Road Kells Co Meath Ireland	EU Representative
GRI Medical & Electronic Technology Co., Ltd 1805 Honggao Road Jiaxing Zhejiang 314031 China	ETO Sterilization Manufacture
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	ETO Sterilization

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**USA**

Subcontractor:	Service(s) supplied
La Ada de Acuna S. De. R.L. De C.V. Av. Hidalgo No. 6 Esq., Blvd. Luis Donaldo Colosio Col. Educativa, Nogales Sonora 84093 Mexico	Manufacture
Lianyungang Aiyeh Non-Woven Products Co., Ltd No. 9 YunYang Rd. Huangjiuni Export Processing Zone Lianyungang, Jiangsu 222047 China	Manufacture
Master & Frank (Pinghu) Ent. Co., Ltd. No. 2000, Xingping II Rd. Pinghu Economic Development Zone Zhejiang P.R. China	Manufacture

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**USA**

Subcontractor:	Service(s) supplied
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	<b>Manufacture</b>
O&M Halyard, Inc. 5405 Windward PKWY Alpharetta Georgia 3004 USA	<b>Regulatory Compliance</b>
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND), LTD. 200 moo 8 Kanchanavanich Road Tambol Prik, Amphur Sadao Songkhla, 90120 Thailand	<b>Manufacture</b>

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**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
Sterigenics S. de R. L. de C. V. James Watt No. 22 Parque Industrial Cuamatla Cuautitlan Izcalli Estado de México C.P. 54730 Mexico	ETO Sterilization
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Gamma Irradiation
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	ETO Sterilization

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**Mechanicsville**  
**Virginia**  
**23116**  
**USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	ETO Sterilization
Sterigenics US, LLC 2971 Olympic Industrial Drive SE Suite 116 Atlanta Georgia 30339 USA	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization

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**Virginia**  
**23116**  
**USA**

### Subcontractor:

### Service(s) supplied

Synergy Health (Thailand) Ltd  
 700/465 Amata Nakorn Industrial Estate  
 Moo 7, Tambol Donhuaroh  
 Amphur Muang  
 Chonburi 20000  
 Thailand

**Gamma Sterilization**

Synergy Sterilisation (M) Sdn Bhd  
 Plot 203  
 Kuala Ketil Industrial Estate  
 Kuala Ketil  
 Kedah  
 09300  
 Malaysia

**Gamma Sterilization**

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# EC Certificate - Production Quality Assurance

## Certificate History

Certificate No: **CE 698961**  
Date: **2019-02-25**  
Issued To: **O & M Halyard, Inc.**  
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**Mechanicsville**  
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Date	Reference Number	Action
18 February 2019	9643055	First Issue.
Current	9643448	Traceable to NB 0086.

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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.

A member of BSI Group of Companies.

# 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

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

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Certificate No: **FM 697013**

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA	The design and development 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.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

Page: 2 of 3

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](http://www.bsigroup.com/ClientDirectory)

To be read in conjunction with the scope above or the attached appendix.

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

Page: 3 of 3

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To be read in conjunction with the scope above or the attached appendix.

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

## EC Declaration of Conformity

**Name of Products:** Surgical Gowns

**Product Codes:** See **Attachment A**

**UMDNS Code:** 11901 (Gowns, Operating Room, Disposable)

**GMDN Code:** 35091 (Operating Room Gown, Single-use)

**Legal Manufacturer (Place of Issue):** Halyard Health, Inc.  
5405 Windward Parkway  
Alpharetta, Georgia (GA) 30004, USA

**EU Authorized Representative:** Halyard Belgium BVBA  
Leonardo Da Vincilaan 1  
1930 Zaventem  
Belgium

**Product Standards:** BS EN 13795:2011

**Start of CE:** See **Attachment A**

**Conformity Assessment Route:** Annex V

**Device Classification, Rules:** Class I (Sterile), as per Rule 1 of Annex IX

**CE certificate number:** CE 621867

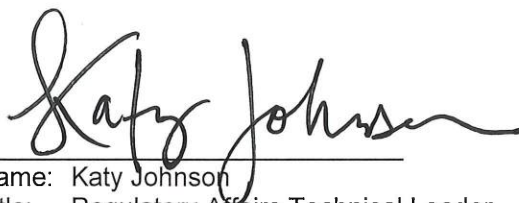
**Notified Body:** BSI (0086)

**Quality System Certificate:** FM 620884 (BSI)

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Directive(s) is retained under the premises of Halyard Health, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

**Authorized Signature:**



Name: Katy Johnson  
Title: Regulatory Affairs Technical Leader  
Halyard Health, Inc.  
Date: 29-Nov-2017



## Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Product Code	Product Description	Sterilization	Start of CE Mark
10550	MicroCool* Breathable High Performance Specialty Gown with Towel, with SECURE-FIT*, XL	Sterile - EO	23-Mar-2015
10558	MicroCool* Breathable High Performance Specialty Gown with Towel, with SECURE-FIT*, L	Sterile - EO	23-Mar-2015
10566	MicroCool* Breathable High Performance Specialty Gown with Towel, SECURE-FIT*, XXL	Sterile - EO	23-Mar-2015
11783	HALYARD BASICS* Surgical Gown, L, with Towels	Sterile - EO	23-Mar-2015
11784	HALYARD BASICS* Surgical Gown, XL, with Towels	Sterile - EO	23-Mar-2015
13337	HALYARD BASICS* Surgical Gown, X-Large, XX-Long with Towels	Sterile - EO	23-Mar-2015
13359	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, S	Sterile - EO	23-Mar-2015
13815	HALYARD BASICS* Fabric-Reinforced Surgical Gown, X-Large, XX-Long, with Towels	Sterile - EO	23-Mar-2015
40989	MicroCool* Breathable High Performance Gown with Towels, Large	Sterile - EO	23-Mar-2015
40998	MicroCool* Breathable High Performance Gown with Towels, XL	Sterile - EO	23-Mar-2015
41000	MicroCool* Breathable High Performance Gown with Towels, L, X-Long	Sterile - EO	23-Mar-2015
41004	MicroCool* Breathable High Performance Gown with Towels, XL, X-Long	Sterile - EO	23-Mar-2015
41928	Aero Blue* Performance Surgical Gown with Towels, L	Sterile - EO	19-Jul-2016
41929	Aero Blue* Performance Surgical Gown with Towels, XL	Sterile - EO	19-Jul-2016
41930	Aero Blue* Performance Surgical Gown with Towels, L, X-Long	Sterile - EO	19-Jul-2016
41931	Aero Blue* Performance Surgical Gown with Towels, XL, X-Long	Sterile - EO	19-Jul-2016
41935	Aero Blue* Performance Surgical Gown with Mask and Towel, S	Sterile - EO	19-Jul-2016
41936	Aero Blue* Performance Surgical Gown with Mask and Towel, L	Sterile - EO	19-Jul-2016
41937	Aero Blue* Performance Surgical Gown with Mask and Towel, XL	Sterile - EO	19-Jul-2016
41938	Aero Blue* Performance Surgical Gown with Mask and Towel, XXL	Sterile - EO	19-Jul-2016
76240	Surgical Gown Pack	Sterile - EO	23-Mar-2015
41870	Aero Blue* Performance Surgical Gown with Blue Huck Towel, S	Sterile - EO	19-Jul-2016
41871	Aero Blue* Performance Surgical Gown with Blue Huck Towel, L	Sterile - EO	19-Jul-2016
41872	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XL	Sterile - EO	19-Jul-2016
41873	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XXL	Sterile - EO	19-Jul-2016
41874	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XXXL	Sterile - EO	19-Jul-2016
42620	Aero Blue* Performance Surgical Gown with Blue Huck Towel, L, X-Long	Sterile - EO	19-Jul-2016
42621	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XL, X-Long	Sterile - EO	19-Jul-2016
43939	Aero Blue* Performance Surgical Gown with Towels, XXL, X-Long	Sterile - EO	19-Jul-2016



Product Code	Product Description	Sterilization	Start of CE Mark
43940	Aero Blue* Performance Surgical Gown with Blue Huck Towel, XXL, X-Long	Sterile - EO	19-Jul-2016
43942	Aero Blue* Performance Surgical Gown with Towels, XXL	Sterile - EO	19-Jul-2016
77456	Gown Pack I	Sterile - EO	23-Mar-2015
78940	Surgical Gown with Set-In Sleeves, 2 Towels (Medium)	Sterile - EO	23-Mar-2015
78945	Surgical Gown with Set-In Sleeves, Large	Sterile - EO	23-Mar-2015
78950	Surgical Gown with Set-In Sleeves, XL	Sterile - EO	23-Mar-2015
78955	Surgical Gown with Set-In Sleeves, 2 Towels (XXL)	Sterile - EO	23-Mar-2015
89791	Sterile Sleeve, 6 in. x 23.5 in. / 15 cm x 59 cm	Sterile - EO	23-Mar-2015
90002	Surgical Gown, Small,	Sterile - EO	23-Mar-2015
90003	Surgical Gown, Small/Medium	Sterile - EO	23-Mar-2015
90012	Surgical Gown, Large	Sterile - EO	23-Mar-2015
90013	Surgical Gown, Large, X-Long	Sterile - EO	23-Mar-2015
90016	Surgical Gown, Large, with Towels	Sterile - EO	23-Mar-2015
90018	Surgical Gown, Large	Sterile - EO	23-Mar-2015
90019	Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90042	Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
90043	Surgical Gown, X-Large, X-Long	Sterile - EO	23-Mar-2015
90046	Surgical Gown, X-Large, with Towels	Sterile - EO	23-Mar-2015
90048	Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
90049	Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90050	Surgical Gown, XX-Large	Sterile - EO	23-Mar-2015
90112	Fabric-Reinforced Surgical Gown, Large, with Towels	Sterile - EO	23-Mar-2015
90113	Fabric-Reinforced Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90138	Surgical Gowns with Huck Towels Twin Pack (Size L & XL)	Sterile - EO	23-Mar-2015
90142	Fabric-Reinforced Surgical Gown, X-Large, with Towels	Sterile - EO	23-Mar-2015
90143	Fabric-Reinforced Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
90363	ULTRA Fabric-Reinforced Surgical Gown, Large, X-Long	Sterile - EO	23-Mar-2015
90373	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long	Sterile - EO	23-Mar-2015
92038	MicroCool* Breathable High Performance Gown with Towel, L, X-Long	Sterile - EO	23-Mar-2015
92042	MicroCool* Breathable High Performance Gown with Towel, XL, X-Long	Sterile - EO	23-Mar-2015
92320	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, L	Sterile - EO	23-Mar-2015
92321	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, XL	Sterile - EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
92323	MicroCool* Breathable High Performance Gown with Blue Huck Towel, with SECURE-FIT*, XXL	Sterile - EO	23-Mar-2015
92330	MicroCool* Breathable High Performance Specialty Gown with Blue Huck Towel, with SECURE-FIT*, L, X-Long	Sterile - EO	23-Mar-2015
92331	MicroCool* Breathable High Performance Specialty Gown with Blue Huck Towel, with SECURE-FIT*, XL, X-Long	Sterile - EO	23-Mar-2015
92333	MicroCool* Breathable High Performance Specialty Gown with Blue Huck Towel, with SECURE-FIT*, XXL, X-Long	Sterile - EO	23-Mar-2015
92336	MicroCool* Breathable High Performance Gown with Towel, Small	Sterile - EO	23-Mar-2015
92338	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, S	Sterile - EO	23-Mar-2015
92340	MicroCool* Breathable High Performance Gown with Towel, L	Sterile - EO	23-Mar-2015
92342	MicroCool* Breathable High Performance Gown with Towel, XL	Sterile - EO	23-Mar-2015
92344	MicroCool* Breathable High Performance Gown with Towel, XXL	Sterile - EO	23-Mar-2015
92347	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, XXXL	Sterile - EO	23-Mar-2015
92351	MicroCool* Breathable High Performance Specialty Gown with Towel, L	Sterile - EO	23-Mar-2015
92353	MicroCool* Breathable High Performance Specialty Gown with Towel, XL	Sterile - EO	23-Mar-2015
92354	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, L	Sterile - EO	23-Mar-2015
92355	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, XL	Sterile - EO	23-Mar-2015
92357	MicroCool* Breathable High Performance Specialty Gown with Towel, XXL	Sterile - EO	23-Mar-2015
92358	MicroCool* Breathable High Performance Gown with Towel, with SECURE-FIT*, XXL	Sterile - EO	23-Mar-2015
95101	ULTRA Surgical Gown, Small, with Polypropylene Fabric and Towel	Sterile - EO	23-Mar-2015
95111	ULTRA Surgical Gown, Large, with Polypropylene Fabric and Towel	Sterile - EO	23-Mar-2015
95113	ULTRA Surgical Gown, Large, with Towels	Sterile - EO	23-Mar-2015
95114	ULTRA Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
95121	ULTRA Surgical Gown, X-Large, with Polypropylene Fabric and Towel	Sterile - EO	23-Mar-2015
95123	ULTRA Surgical Gown, X-Large, with Towels	Sterile - EO	23-Mar-2015
95124	ULTRA Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
95131	ULTRA Surgical, XX-Large	Sterile - EO	23-Mar-2015
95201	ULTRA Fabric-Reinforced Surgical Gown, Small	Sterile - EO	23-Mar-2015
95211	ULTRA Fabric-Reinforced Surgical Gown, Large	Sterile - EO	23-Mar-2015
95221	ULTRA Fabric-Reinforced Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
95224	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long	Sterile - EO	23-Mar-2015
95311	ULTRA Zoned-Impervious Surgical Gown, Large	Sterile - EO	23-Mar-2015
95321	ULTRA Zoned-Impervious Surgical Gown, X-Large	Sterile - EO	23-Mar-2015
95331	ULTRA Zoned-Impervious Surgical Gown, XX-Large	Sterile - EO	23-Mar-2015
95411	ULTRA Film-Reinforced Surgical Gown, Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015



Product Code	Product Description	Sterilization	Start of CE Mark
95421	ULTRA Film-Reinforced Surgical Gown, X-Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015
95431	ULTRA Film-Reinforced Surgical Gown, XX-Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015
95511	ULTRA Film-Reinforced Specialty Gown, Large, with Polypropylene Fabric	Sterile - EO	23-Mar-2015
95521	ULTRA Film-Reinforced Specialty Gown, X-Large, with Polypropylene	Sterile - EO	23-Mar-2015
95531	ULTRA Specialty Gown, XX-Large	Sterile - EO	23-Mar-2015
99294	HALYARD BASICS* Surgical Gown, Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
99295	HALYARD BASICS* Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO	23-Mar-2015
44672	Aero Chrome* Breathable Performance Surgical Gown with Towel, S	Sterile - EO	10-Aug-2017
44673	Aero Chrome* Breathable Performance Surgical Gown with Towel, L	Sterile - EO	10-Aug-2017
44674	Aero Chrome* Breathable Performance Surgical Gown with Towel, XL	Sterile - EO	10-Aug-2017
44675	Aero Chrome* Breathable Performance Surgical Gown with Towel, XXL	Sterile - EO	10-Aug-2017
44676	Aero Chrome* Breathable Performance Surgical Gown with Towel, XXXL	Sterile - EO	10-Aug-2017
44677	Aero Chrome* Breathable Performance Surgical Gown with Towel, L, X-Long	Sterile - EO	10-Aug-2017
44678	Aero Chrome* Breathable Performance Surgical Gown with Towel, XL, X-Long	Sterile - EO	10-Aug-2017
44679	Aero Chrome* Breathable Performance Surgical Gown with Towel, XXL, X-Long	Sterile - EO	10-Aug-2017
44680	Aero Chrome* Breathable High Performance Surgical Gown, S (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44681	Aero Chrome* Breathable High Performance Surgical Gown, L (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44682	Aero Chrome* Breathable High Performance Surgical Gown, XL (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44683	Aero Chrome* Breathable High Performance Surgical Gown, XXL (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44684	Aero Chrome* Breathable High Performance Surgical Gown, XXXL (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44685	Aero Chrome* Breathable High Performance Surgical Gown, L, X-Long (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44686	Aero Chrome* Breathable High Performance Surgical Gown, XL, X-Long (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44687	Aero Chrome* Breathable High Performance Surgical Gown, XXL, X-Long (Blue Huck Towel)	Sterile - EO	25-Aug-2016
44688	Aero Chrome* Breathable High Performance Surgical Gown, S (with Towels)	Sterile - EO	25-Aug-2016
44689	Aero Chrome* Breathable High Performance Surgical Gown, L (with Towels)	Sterile - EO	25-Aug-2016
44690	Aero Chrome* Breathable High Performance Surgical Gown, XL (with Towels)	Sterile - EO	25-Aug-2016
44691	Aero Chrome* Breathable High Performance Surgical Gown, XXL (with Towels)	Sterile - EO	25-Aug-2016
44692	Aero Chrome* Breathable High Performance Surgical Gown, XXXL (with Towels)	Sterile - EO	25-Aug-2016
44693	Aero Chrome* Breathable High Performance Surgical Gown, L, X-Long (with Towels)	Sterile - EO	25-Aug-2016
44694	Aero Chrome* Breathable High Performance Surgical Gown, XL, X-Long (with Towels)	Sterile - EO	25-Aug-2016
44695	Aero Chrome* Breathable High Performance Surgical Gown, XXL, X-Long (with Towels)	Sterile - EO	25-Aug-2016

Product Code	Product Description	Sterilization	Start of CE Mark
46665	ValueSelect* Standard Surgical Gown with Towels, M	Sterile - EO	05-Jan-2017
46666	ValueSelect* Standard Surgical Gown with Towels, L	Sterile - EO	05-Jan-2017
46667	ValueSelect* Standard Surgical Gown with Towels, XL	Sterile - EO	05-Jan-2017
46668	ValueSelect* Standard Surgical Gown with Towels, XXL	Sterile - EO	05-Jan-2017
46673	ValueSelect* Film-Reinforced Surgical Gown with Towels, M	Sterile - EO	05-Jan-2017
46674	ValueSelect* Film-Reinforced Surgical Gown with Towels, L	Sterile - EO	05-Jan-2017
46675	ValueSelect* Film-Reinforced Surgical Gown with Towels, XL	Sterile - EO	05-Jan-2017
46676	ValueSelect* Film-Reinforced Surgical Gown with Towels, XXL	Sterile - EO	05-Jan-2017
47285	ValueSelect* Standard Surgical Gown with Towels, L, X-Long	Sterile - EO	29-Nov-2017
47286	ValueSelect* Standard Surgical Gown with Towels, XL, X-Long	Sterile - EO	29-Nov-2017
47287	ValueSelect* Film-Reinforced Surgical Gown with Towels, L, X-Long	Sterile - EO	29-Nov-2017
47288	ValueSelect* Film-Reinforced Surgical Gown with Towels, XL, X-Long	Sterile - EO	29-Nov-2017

# TECHNICAL DATA SHEET



## Description:

90002: Surgical Gown, S  
90012: Surgical Gown, L  
90042: Surgical Gown, XL  
90013: Surgical Gown, L ,X-Long  
90043: Surgical Gown, XL, X-Long

SMS Fabric, Raglan sleeves, Adjustable Neckline – Hook and Loop,  
Yellow Binding, Drop fold. With 1 Hand Towel.

## Dimensions:

	90002	90012	90042	90013	90043
Length (front, neck to bottom)	105 cm	113 cm	117 cm	134 cm	142 cm
Length (back, neck to bottom)	114 cm	123 cm	127 cm	145 cm	150 cm
Sleeve length (underarm to cuff)	53 cm	57 cm	63 cm	54 cm	62 cm
Neck length (overall)	55 cm	57 cm	63 cm	71 cm	69 cm
Body width (overall)	142 cm	156 cm	174 cm	154 cm	174 cm

## Properties:

Basis weight of base material: 44 g/m<sup>2</sup>  
Standard Performance Gown as defined by EN 13795.  
Test results as per EN 13795 available upon request.

## Indication:

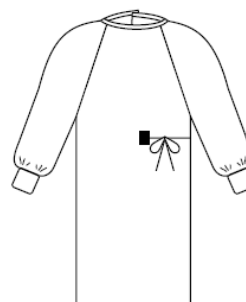
To prevent the transfer of infective agents between the operating  
room personnel and the patient.  
Single use product.

## Counter indication:

None in particular.

## Main materials:

Base material: SMS Fabric (polypropylene), topically treated for  
alcohol repellency and static dissipation.  
Cuffs and Threads: Polyester  
Hook and Loop Fastener: Nylon, Polyethylene  
Does not contain Natural rubber latex.  
Does not contain DEHP.



## Sterilization:

Products are sterilized by ethylene oxide (ETO).

## Packaging:

90002: Shipping case of 36 units.  
90012: Shipping case of 36 units.  
90042: Shipping case of 34 units.  
90013: Shipping case of 34 units.  
90043: Shipping case of 34 units.

All units are placed within 1 polyethylene bag.  
Unit packaging: CSR Wrap, FFS (Form/Fill/Seal) peel-bag,  
1 traceability sticker. Bar coding: GS1-128 symbology, linear, on  
shipping case and unit packaging.

## Manufacturing:

Products are manufactured in China or Honduras.  
The quality system of the manufacturing sites is ISO 13485 compliant.

## Regulatory information:

Products CE marked as per 93/42/EEC Directive on Medical Devices.  
Class of the device: I, sterile.  
These products are EN 13795 compliant.

## Storage:

Store in a dry and cool place, away from intense sources of heat.  
Keep as much as practicably possible in its shipper box.

## Shelf life:

5 years, from date of manufacture.

# TECHNICAL DATA SHEET

## Description

### Reference

77794 U-Bar Pack VI, Sterile

### Components

CSR Wrap 96 x 96 cm	1
BTC ZONE-REINFORCED 152 x 229 cm	1
MAYO STAND COVER REINFORCED 80 x 145 cm	1
ABSORBENT TOWEL 38 x 56 cm	1
SUTURE BAG	1
U-DRAPE 193 x 305 cm (Split 10 x 101 cm)	1
BAR DRAPE W/ ABC 157 x 268 cm	1

### Properties

Basis weight of Drapes: 47 g/m<sup>2</sup>, Reinforcement: 99 g/m<sup>2</sup>

Thickness and basis weight of BTC: Film 57µm + SMS 22 g/m<sup>2</sup>

Thickness and basis weight of MAYO: Film 57µm + SMS 47 g/m<sup>2</sup>

U-Drape and Bar Drape: High performance drapes as defined by EN 13795:2011.

Test results as per EN13795 available upon request.

## Indication

To create a sterile field around the operative site and to cover areas of the body and operating room equipment that may or may not be involved in the surgical procedure. Single use product.

## Counter Indication

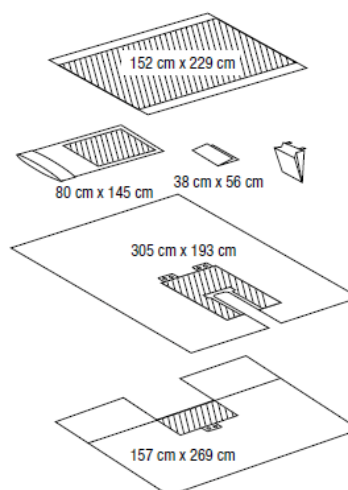
None in particular

## Main Materials

Drapes: SMS fabric with Control Plus SMF (polypropylene)  
 Back Table Cover (BTC): Film/ SMS (polyethylene/polypropylene)  
 MAYO: Film/ SMS (polyethylene/polypropylene)  
 Absorbent Towel: Polyester, Polyolefin coated  
 Not formulated with Natural rubber latex.  
 Not formulated with DEHP.

## Sterilisation

Sterilized by ethylene oxide (ETO)



## Packaging

Shipping case of 9 units.

All units are placed within 1 polyethylene bag.

Unit packaging: Clear Header Bag, 1 traceability sticker.

Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

## Manufacturing

Non-woven manufactured in the USA, assembled in Mexico.

The quality system of the manufacturing site is ISO 13485 compliant.

## Regulatory Information

Product CE marked as per 93/42/EEC Directive on Medical Devices.

Class of the device: I

This product complies with EN 13795:2011.

Notified body: BSI (0086)

## Storage Information

Store in a dry and cool place, away from intense sources of heat.

Keep as much as practicably possible in its shipper box.

## Shelf Life

5 years, from date of manufacture



# TECHNICAL DATA SHEET

## Description:

88900: Halyard Basics\* Universal Pack I, Sterile

### Components:

BACK TABLE COVER 152 x 191 cm	1
MAYO STAND COVER 80 x 144 cm	1
TAPE STRIP 10 x 55 cm	1
ABSORBENT TOWEL 38 x 56 cm	1
SIDE DRAPE 90 x 100 cm	2
BOTTOM DRAPE 195 x 195 cm	1
TOP DRAPE 275 X 150 cm	1

### Properties:

Basis weight of Drapes: 40 g/ m<sup>2</sup> Reinforcement: 85 g/ m<sup>2</sup>

Basic weight of MAYO: Film 40 g/m<sup>2</sup> + Spunbond 25 g/m<sup>2</sup>

Basis weight of BTC: Film 50 g/m<sup>2</sup> + Spunbond 35 g/m<sup>2</sup>

Standard performance drapes as defined by EN 13795:2011.

Test results as per EN13795 available upon request.

## Indication:

To create a sterile field around the operative site and to cover areas of the body and operating room equipment that may or may not be involved in the surgical procedure. Single use product.

## Counter indication:

None in particular.

## Main materials:

Drapes: SMS fabric with Reinforcement (Spunbond/PE film)

Mayo Stand Cover (MAYO): Spunbond/PE Film

Back Table Cover (BTC): Laminated Material (Spunbond/PE film)

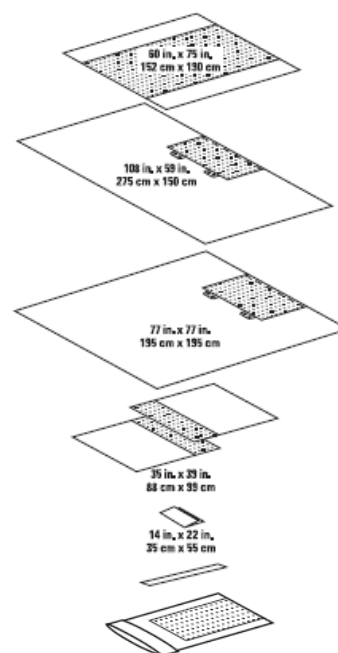
Absorbent Towel: Polyester, Polyolefin coated

Not formulated with Natural rubber latex.

Not formulated with DEHP.

## Sterilization:

Product is sterilized by ethylene oxide (ETO).



## Packaging:

Shipping case of 5 units.

All units are placed within 1 polyethylene bag.

Unit packaging: Clear Header Bag, 2 traceability stickers.

Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

## Manufacturing:

Product is manufactured in China.

The quality system of the manufacturing sites is ISO 13485 compliant.

## Regulatory information:

Product CE marked as per 93/42/EEC Directive on Medical Devices.

Class of the device: I, sterile. Notified body: BSI (0086).

This product complies with EN 13795:2011.

## Storage:

Store in a dry and cool place, away from intense sources of heat.

Keep as much as practicably possible in its shipper box.

## Shelf life:

5 years, from the date of manufacture.

# TECHNICAL DATA SHEET



## Description

### Reference

49214: TECNOL\* Fog-Free Surgical Mask/Blue

49215: TECNOL\* Anti-Fog Surgical Mask

With DERMA-TOUCH\* Tape/Green

Pleat- Style with Ties

Single Use Only

### Dimensions

Length: 17.8 cm

Width: 9.5 cm

Tie length: 83 cm

### Properties

Bacterial Filtration Efficiency (BFE): >98%

Differential Pressure: <29.4 Pa

Type II mask as defined by EN 14683.

## Main Materials

Does not contain Natural Rubber Latex.

Does not contain DEHP.

Outside layer: Polypropylene Spunbond White

Middle layer: Base Filter Media (Polypropylene)

Inside layer: Cellulose Tissue, White

Nose piece: Flat Aluminum Wire

Ties: Polypropylene

49214- Foam band: Polyester, Blue

49215- Derma-Touch Tape: Clear Polyethylene film, anti-fog

## Sterilisation

These products are non-sterile.

These products cannot be sterilized.

## Packaging

Shipping case of 300 units.

50 units are placed within 1 dispenser and 6 dispensers are placed within a shipping case.

Bar coding: GS1-128 symbology, linear, on shipping case and dispenser boxes.



## Manufacturing

Materials manufactured in the USA.

Product assembled in Mexico.

## Regulatory Information

Product CE marked as per 93/42/EEC Directive on Medical Devices.

Class of the device: I.

Product compliant with EN14683.

## Storage Information

Store in a dry and cool place, away from intense sources of heat.

Keep the masks as much as practicably possible in their dispenser box.

Keep dispenser boxes as much as practicably possible in their shipper box.

## Shelf Life

49214: None specified.

49215-01: 3 years, from date of manufacture, 49215-37: None specified.

# TECHNICAL DATA SHEET



## Description

### Reference

69801: Bouffant Cap, Blue, Large, Non-Sterile  
69803: Bouffant Cap, Blue, X-Large, Non-Sterile

1-Layer Spunbond Fabric, Elastic to Gather the Cap around the Head,  
No Potential Fluid Contact.

### Dimensions

	<i>L</i>	<i>XL</i>
Opening Relaxed:	20.3 cm	22.9 cm
Opening Stretched:	61.0 cm	68.6 cm

### Properties

Basis weight of base material: 14 g/m<sup>2</sup>

## Indication

Bouffant caps are worn in hospitals to contain hair of the wearer to prevent transmission of bacteria from falling hair.  
Single use product.

## Counter indication

None in particular.

## Main materials

Base material: Untreated Spunbond (polypropylene)  
Thread: Polyester  
Closure: Elastic  
Does not contain Natural rubber latex.  
Does not contain DEHP.

## Sterilisation

Products are non-sterile.



## Packaging

69801, 69803: Shipping case of 500 units.  
100 units are placed within 1 dispenser and 5 dispensers are placed within a shipping case.  
Bar coding: GS1-128 symbology, linear, on shipping case and dispensers.

## Manufacturing

Products are manufactured in China.  
The quality system of the manufacturing sites is ISO 13485 compliant.

## Regulatory information

Product CE marked as per 93/42/EEC Directive on Medical Devices.  
Class of the device: I.

## Storage

Store in a dry and cool place, away from intense sources of heat.  
Keep as much as practicably possible in its shipper box.

## Shelf life

None specified.