By Royal Charter

# 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**

Digitally signed by Dubalari Pavel
Date: 2021.06.03 10:54:21 EEST
Reason: MoldSign Signature
Location: Moldova

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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# EC Certificate - Production Quality Assurance

**Supplementary Information to CE 698961**

Issued To:

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

| Number | Device Name | Intended Purpose per IFU |
|---|---|---|
| **Class IIa** | | |
| MD 0101 | Transurethral Resection (T.U.R.) Drapes & Packs | N/A |
| **Class Is** | | |
| 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**

By Royal Charter

# 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** |
| Date: | **2019-02-25** |
| Issued To: | **O & M Halyard, Inc.**<br>**9120 Lockwood Blvd**<br>**Mechanicsville**<br>**Virginia**<br>**23116**<br>**USA** |

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

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# EC Certificate - Production Quality Assurance

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

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| Date: | **2019-02-25** |
| Issued To: | **O & M Halyard, Inc.**<br>**9120 Lockwood Blvd**<br>**Mechanicsville**<br>**Virginia**<br>**23116**<br>**USA** |

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

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# EC Certificate - Production Quality Assurance

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

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| Issued To: | **O & M Halyard, Inc.**<br>**9120 Lockwood Blvd**<br>**Mechanicsville**<br>**Virginia**<br>**23116**<br>**USA** |

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

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# EC Certificate - Production Quality Assurance

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

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| Issued To: | **O & M Halyard, Inc.**<br>**9120 Lockwood Blvd**<br>**Mechanicsville**<br>**Virginia**<br>**23116**<br>**USA** |

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

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# EC Certificate - Production Quality Assurance

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

# List of Significant Subcontractors

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| Issued To: | **O & M Halyard, Inc.**<br>**9120 Lockwood Blvd**<br>**Mechanicsville**<br>**Virginia**<br>**23116**<br>**USA** |

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

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# EC Certificate - Production Quality Assurance

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

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| Issued To: | **O & M Halyard, Inc.**<br>**9120 Lockwood Blvd**<br>**Mechanicsville**<br>**Virginia**<br>**23116**<br>**USA** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Synergy Health (Thailand) Ltd<br>700/465 Amata Nakorn Industrial Estate<br>Moo 7, Tambol Donhuaroh<br>Amphur Muang<br>Chonburi 20000<br>Thailand | **Gamma Sterilization** |
| Synergy Sterilisation (M) Sdn Bhd<br>Plot 203<br>Kuala Ketil Industrial Estate<br>Kuala Ketil<br>Kedah<br>09300<br>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.**
**9120 Lockwood Blvd**
**Mechanicsville**
**Virginia**
**23116**
**USA**

| Date | Reference Number | Action |
|---|---|---|
| 18 February 2019 | 9643055 | First Issue. |
| Current | 9643448 | Traceable to NB 0086. |

By Royal Charter

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

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

Certificate No: **FM 697013**

| Location | Registered Activities |
|---|---|
| La Ada de Acuna<br>Kim. 4.5 Carreterra Presa La Amistad<br>Ciudad De Acuna<br>Coahuila<br>26220<br>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<br>AV. Hidalgo #6 Esq., Blvd.,<br>Luis Donaldo Colosio, Col. Educativa<br>Nogales Sonora<br>84093<br>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<br>(Thailand) Ltd.<br>200 Moo 8, Kanchanavanich Road,<br>Tambol Prik, Amphur Sadao,<br>Songkhla<br>90120<br>Thailand | The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves. |

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

HALYARD

# EC Declaration of Conformity

| | |
|---|---|
| **Name of Products:** | Apparel |
| **Product Codes:** | See **Attachment A** |
| **UMDNS Code:** | 13574 (Cover,Shoe)<br>13882 (Surgical Head Coverings)<br>11897 (Gowns, disposable)<br>11901 (Gowns, Operating Room, Disposbale) |
| **GMDN Code:** | 15056 (Non-conductive shoe cover)<br>43315 (Surgical Hood)<br>32297 (Cap, Surgical, Single Use)<br>35092 (Gowns, Patient, Single Use)<br>35091 (Gown, Operating Room, Single Use)<br>58382 (Disposable scrub suit, non-sterile) |
| **Legal Manufacturer (Place of Issue):** | O&M Halyard, Inc.<br>9120 Lockwood Blvd.<br>Mechanicsville, Virginia (VA) 23116, USA |
| **EU Authorized Representative:** | Arc Royal<br>Virginia Road Kells, Co<br>Meath, Ireland |
| **Product Standards:** | N/A |
| **Start of CE:** | 09-Dec-2014 |
| **Conformity Assessment Route:** | Annex VII |
| **Device Classification, Rules:** | Class I per Annex IX |
| **Quality System Certificate:** | FM 697013 (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 O&M Halyard, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

**Authorized Signature:**

Angela L Bunn 10-APR-19

Name: Angela L. Bunn, RAC

Title: Director, Regulatory Affairs Global Products Division
O&M Halyard, Inc.

HALYARD

# Attachment A (Product List)

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

| Product Code | Product Description | Sterilization |
|---|---|---|
| 69114 | BASICS* Shoe Cover, Regular Size, Blue | Non-sterile |
| 69121 | BASICS* Shoe Cover, XL, Blue | Non-sterile |
| 69252 | X-TRA TRACTION* Shoe Cover, Universal Size, Blue | Non-sterile |
| 69253 | ANKLE GUARD* Shoe Cover, Universal Size, Blue | Non-sterile |
| 69254 | X-TRA TRACTION* Shoe Cover Blue, X-Large | Non-sterile |
| 69353 | ANKLE GUARD* Shoe Cover, X-Large, Blue | Non-sterile |
| 69551 | Heavy Duty Shoe Cover, Universal Size, Blue | Non-sterile |
| 69571 | HI GUARD* Regular Full Coverage Boot, Universal Size | Non-sterile |
| 69572 | HI GUARD* Ultra Full Coverage Boot, Universal Size | Non-sterile |
| 69671 | HI GUARD* Regular Full Coverage Boot, X-Large | Non-sterile |
| 69672 | HI GUARD* Ultra Full Coverage Boot, X-Large | Non-sterile |

HALYARD

| Product Code | Product Description | Sterilization |
|---|---|---|
| 44648 | Bloodborne Pathogen Protection Hood | Non-Sterile |
| 69110 | Protective Surgical Hood, Universal Size, Blue | Non-sterile |
| 69240 | Surgical Cap, KAYCEL* Fabric, Universal Size, Blue | Non-sterile |
| 69801 | Spunbond Bouffant Cap, L Blue | Non-sterile |
| 69803 | Spunbond Bouffant Cap, XL, Blue | Non-sterile |
| 54100 | Tri-Layer AAMI1 Isolation Gown, Yellow, Large | Non-sterile |
| 54101 | Tri-Layer AAMI1 Isolation Gown, Yellow, X-Large | Non-sterile |
| 54110 | Tri-Layer AAMI1 Isolation Gown, Blue, Medium | Non-sterile |
| 54111 | Tri-Layer AAMI1 Isolation Gown, Blue, X-Large | Non-sterile |
| 54310 | Tri-Layer AAMI3 Isolation Gown, Blue, Large | Non-sterile |
| 54311 | Tri-Layer AAMI3 Isolation Gown, Blue, X-Large | Non-sterile |
| 69025 | Procedure Gown / Blue / Large | Non-sterile |
| 69028 | Procedure Gown / Blue / X-Large | Non-sterile |
| 69124 | Cover Gown, Yellow, L | Non-sterile |
| 69125 | Cover Gown, Yellow, XL | Non-sterile |
| 69127 | Cover Gown, Blue, L | Non-sterile |
| 69129 | Cover Gown, Blue, XL | Non-sterile |
| 69190 | Tri-Layer AAMI2 Isolation Gown, L, Yellow | Non-sterile |
| 69191 | Tri-Layer AAMI2 Isolation Gown, XL, Yellow | Non-sterile |
| 69316 | Film Gown, Blue, Open Back, Thumb Hooks, Extra-Large | Non-sterile |
| 69455 | Impervious Open-Back Gown / Blue / Knit Cuffs / Large | Non-sterile |
| 69490 | Film Gown, Blue, Open Back, Thumb Hooks, Universal Size | Non-sterile |
| 69600 | Impervious Comfort Gown / Blue / Knit Cuffs / Large Size | Non-sterile |
| 69601 | Impervious Comfort Gown / Blue / Knit Cuffs / XX-Large | Non-sterile |
| 69602 | Impervious Comfort Gown / Blue / Thumb Hooks / Large | Non-sterile |
| 69603 | Impervious Comfort Gown / Blue / Thumb Hooks / XX-Large | Non-sterile |
| 69766 | Patient Gown | Non-sterile |
| 69979 | Tri-Layer AAMI2 Isolation Gown, Yellow, Large | Non-sterile |
| 69981 | Tri-Layer AAMI2 Isolation Gown, Blue, Large | Non-sterile |

HALYARD

| Product Code | Product Description | Sterilization |
|---|---|---|
| 69986 | Tri-Layer AAMI2 Isolation Gown, Yellow/Elastic Cuff, Large | Non-sterile |
| 69987 | Tri-Layer AAMI2 Isolation Gown, Blue, X-Large | Non-sterile |
| 69988 | Tri-Layer AAMI2 Isolation Gown, Yellow, X-Large | Non-sterile |
| 69989 | Tri-Layer AAMI2 Isolation Gown, Yellow, X-Large | Non-sterile |
| 79002 | Patient Robe, Universal Size | Non-Sterile |
| 69350 | General Purpose Apron | Non-Sterile |
| 69701 | Scrub Shirt, Blue, Medium | Non-Sterile |
| 69702 | Scrub Shirt/Blue/Large | Non-Sterile |
| 69703 | Scrub Shirt/Blue/X-Large | Non-Sterile |
| 69704 | Scrub Shirt/Blue/X-Large | Non-Sterile |
| 69711 | Scrub Shirt/Pants/Medium | Non-Sterile |
| 69712 | Scrub Shirt/Blue/Large | Non-Sterile |
| 69713 | Scrub Shirt/Blue/X-Large | Non-Sterile |
| 69714 | Scrub Shirt/Blue/XX-Large | Non-Sterile |

By Royal Charter

# EC Certificate - Production Quality Assurance

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

**No.** **CE 540596**

Issued To: **Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

In respect of:

**Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory, non-active gynaecological, non-active regional anaesthesia, non-active surgical and non-active urology devices.**
**Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.**
**The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy, bone lesion biopsy and non-active sterile urology catheters.**

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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# EC Certificate - Production Quality Assurance

**Supplementary Information to CE 540596**

Issued To:

**Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Number | Device Name | Intended purpose per IFU |
|---|---|---|
| **Class IIa** | | |
| MD 0102 | Sterile Intraosseous Vascular Access System | -- |
| MD 1104 | Non-sterile Intraosseous Vascular Access System | |
| MD 0102 | Sterile Powered Bone Access | -- |
| MD 1104 | Non-sterile Powered Bone Access | |
| MD 0102 | Sterile Sternal Intraosseous Device | -- |
| MD 0101 | Sterile Silicone Foley Catheter | -- |

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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# EC Certificate - Production Quality Assurance

**Supplementary Information to CE 540596**

Issued To:

**Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Number | Device Name | Intended purpose per IFU |
|---|---|---|
| **Class Is** | | |
| MD 0301 | Intraosseous Vascular Access System Stabilizer | -- |
| MD 0102 | Powered bone access connector | -- |
| MD 0101 | Tracheostomy Tube Accessories | -- |
| MD 0102 | Tuohy Borst Adaptor | -- |
| MD 0102 | Syringe | -- |
| MD 0101 | Urology Dilator | -- |
| MD 0101 | Guedel Airway | -- |
| MD 0101 | Intrauterine Catheter Set | -- |
| MD 0101 | Sterile Container | -- |
| MD 0101 | Neckband | -- |
| **Sterility aspects only** | | |
| --- | Procedure Packs under article 12 | --- |

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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# EC Certificate - Production Quality Assurance

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

# List of Significant Subcontractors

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|---|---|
| Certificate No: | **CE 540596** |
| Date: | **2020-06-09** |
| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| ArcRoyal<br>Virginia Road<br>Kells, Co. Meath<br>Ireland | **Manufacture** |
| Arriol International Corporation<br>Carretera San Isidro KM 17<br>Zona Franca San Isidro<br>Santo Domingo Este<br>Dominican Republic | **ETO Sterilization**<br>**Manufacture** |
| Arrow International CR, a.s.<br>Jamska 2359/47<br>Zdar Nad Sazavou<br>59101<br>Czech Republic | **Manufacture** |
| BBF Sterilisationsservice GmbH<br>Willy-Rüsch-Straße 10/1<br>71394 Kernen<br>Germany | **Radiation (Gamma Sterilization)** |

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

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| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| CeMed GmbH<br>Im Oberdorf 41<br>72419 Neufra<br>Germany | **Assembly**<br>**Packaging** |
| China Biotech Corporation<br>No. 10, 33 rd., Road,<br>Taichung Industrial Park<br>Taichung<br>Taiwan | **Radiation (Gamma Sterilization)** |
| Degania Silicone Limited<br>Kibbutz<br>1513000 Degania Bet<br>Israel | **Manufacture** |
| Donatelle Plastics, Inc.<br>501 County Road E-2 Extension<br>New Brighton<br>MN 55112<br>USA | **Manufacture** |

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By Royal Charter

# EC Certificate - Production Quality Assurance

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

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| Certificate No: | **CE 540596** |
| Date: | **2020-06-09** |
| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Foremount Enterprise Co., Ltd.<br>No. 17, Alley 15, Lane 5<br>Shenan Street<br>Shengang Dist<br>42944 Taichung City<br>Taiwan | **Manufacture** |
| Iotron Industries USA<br>4394 East Park 30 Drive<br>Columbia City<br>Indiana<br>46725<br>USA | **Radiation (E Beam Sterilization)** |
| Medical Service GmbH<br>Luisenstraße 8<br>75378 Bad Liebenzell/Unterhaugstett<br>Germany | **Assembly**<br>**Packaging** |

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By Royal Charter

# EC Certificate - Production Quality Assurance

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

# List of Significant Subcontractors

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|---|---|
| Certificate No: | **CE 540596** |
| Date: | **2020-06-09** |
| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Mediplast Israel Ltd.<br>7 Hayarkon St.<br>P.O. Box 13214 Industrial Zone<br>Yavne<br>8122710<br>Israel | **ETO Sterilization** |
| Rose GmbH für Medizintechnik<br>Gottbillstraße 25-30<br>54294 Trier<br>Germany | **ETO Sterilization** |
| sfm medical devices GmbH<br>Brückenstraße 5<br>63607 Wächtersbach<br>Germany | **ETO Sterilization**<br>**Manufacture** |

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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 540596** |
| Date: | **2020-06-09** |
| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Sparton Onyx, LLC<br>2920 Kelly Avenue<br>Watertown<br>South Dakota<br>57201-7249<br>USA | **Manufacture** |
| Sterigenics Germany GmbH<br>Kasteler Straße 45<br>Wiesbaden<br>65203<br>Germany | **ETO Sterilization** |
| Sterigenics US, LLC<br>2400 Airport Road<br>Santa Teresa<br>New Mexico<br>88008<br>USA | **ETO Sterilization** |

...making excellence a habit.™

# 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 540596** |
| Date: | **2020-06-09** |
| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Steritec, Inc.<br>P.O. Box 1969<br>1705 Enterprise Street<br>Athens, TX 75751<br>United States of America | **ETO Sterilization** |
| Synergy Health Sterilisation UK Ltd<br>1 Alpha Court<br>Capitol Park<br>Thorne<br>Doncaster<br>DN8 5TZ<br>United Kingdom | **ETO Sterilization** |
| Synergy Sterilisation (M) Sdn Bhd.<br>Plot 203<br>Kuala Ketil Industrial Estate<br>Kuala Ketil<br>Kedah<br>09300<br>Malaysia | **ETO Sterilization** |

...making excellence a habit.™

# 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 540596** |
| Date: | **2020-06-09** |
| Issued To: | **Teleflex Medical**<br>**IDA Business and Technology Park**<br>**Dublin Road**<br>**Athlone**<br>**Co. Westmeath**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Teleflex Medical Sdn. Bhd.<br>Lot PT 2577, Jalan Perusahaan 4<br>34600 Kamunting Perak<br>Malaysia | **ETO Sterilization**<br>**Manufacture** |
| Viant San Antonio, Inc.<br>7027 Fairgrounds Parkway<br>San Antonio<br>TX 78238<br>United States of America | **Manufacture** |
| Viant Upland, Inc.<br>a.t.a. (formerly) Lake Region Medical<br>2052 West 11th Street<br>Upland CA 91786<br>USA | **Manufacture** |
| Willy Rüsch GmbH<br>Willy-Rüsch-Straße 4-10<br>71394 Kernen i.R.,<br>Germany | **Manufacture** |

...making excellence a habit.™

# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Date | Reference Number | Action |
|---|---|---|
| 13 January 2009 | 7245725 | First issue. |
| 17 March 2009 | 7325720 | Company address amended.<br>Extension to scope.<br>Addition of Willy Rüsch, Germany as subcontractor for design and manufacture. |
| 25 August 2009 | 7399908<br><br><br><br>7439096 | Addition of SFM as significant subcontractor for manufacture.<br>Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic.<br>Correction of History page header.<br>Intrauterine catheter added to scope. |
| 08 September 2010 | 7558507 | Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added.<br>Certificate renewal. |

# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Date | Reference Number | Action |
|---|---|---|
| 23 February 2011 | 7635647 | Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.'<br>Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities. |
| 23 May 2012 | 7778468 | Correction of significant subcontractor address. |
| 04 February 2013 | 7932595 | The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC. |
| 13 July 2015 | 8334933 | Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.'<br>Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC. |

# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Date | Reference Number | Action |
|---|---|---|
| 28 August 2015 | 8406492 | Certificate renewal.<br>Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'. |
| 10 February 2016 | 8455693 | Removal of Vidacare LLC from list of significant subcontractors.<br>Service(s) supplied for Arriol International Corporation, Coastal Life Technologies Inc. and Lake Region Medical changed from crucial suppliers to Control of Sterilization, Manufacture.<br>Service(s) supplied for Sparton Onyx. LLC changed from crucial supplier to Manufacture.<br>Removal of repeated use of word 'devices' from scope. |
| 28 July 2017 | 8762518 | Change of address for Coastal Life Technologies.<br>Addition of Donatelle Plastics Inc., 55112 New Brighton to list of significant subcontractors. |
| 04 March 2019 | 7779566 | Traceable to NB 0086. |

# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Date | Reference Number | Action |
|---|---|---|
| Current | 3124053 | Certificate renewal.<br>Addition of supplementary product information table.<br>Update to scope to include non-active sterile urology catheters.<br>Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc<br>Removal of Control of Sterilization from Service(s) supplied for ArcRoyal Ltd., Arrow International CR, a.s. (Zdar), Viant San Antonio, Inc., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Viant Upland, Inc., sfm medical devices GmbH, Teleflex Medical Sdn. Bhd., and Willy Rüsch GmbH.<br>Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd.<br>Administrative correction of details for ArcRoyal, Arriol International Corporation, Arrow International CR, a.s., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Sparton Onyx. LLC, sfm medical devices GmbH, Teleflex Medical Sdn. Bhd. and Willy Rüsch GmbH.<br>Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C.<br>Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging. |

# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
**IDA Business and Technology Park**
**Dublin Road**
**Athlone**
**Co. Westmeath**
**Ireland**

| Date | Reference Number | Action |
|---|---|---|
| | 3124053 | Addition of Degania Silicone Limited for Manufacture<br>Addition of Steritec, Inc., Sterigenics US, LLC, Rose GmbH für Medizintechnik, Synergy Health Sterilisation UK Ltd, Sterigenics Germany GmbH, Mediplast Israel Ltd., and Synergy Sterilisation (M) Sdn Bhd. for ETO Sterilization<br>Addition of Iotron Industries USA for E-beam Sterilization<br>Addition of China Biotech Corporation and BBF Sterilisationsservice GmbH for Gamma Sterilization. |

EC Certificate Full Quality Assurance System: US97/10879.01

The management system of

# Teleflex Medical

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4)**

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 11 September 2018 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 29. Certified since 26 September 2000

Certification is based on reports numbered WWMC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10879.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

# Teleflex Medical

## Directive 93/42/EEC

**on medical devices, Annex II (excluding section 4)**

Issue 29

Detailed scope

Sterile Hem-o-lok Ligation Clips.
Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextStitch®,Capio™, Fixt®, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and FIXT® polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures.
Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.

Sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, EFx endo fascial closuresystem (abdominal access), Sterile, EFx shield fascial closure system (abdominal access), Sterile, EFx classic fascial closuresystem (abdominal access)
Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems,
Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers),Percutaneous surgical System (Interchangeable electrosurgical tool tips) for laparoscopic surgery. Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certificate US97/10878.00

The management system of

# Teleflex Medical

3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

# ISO 13485:2016
# EN ISO 13485:2016

For the following activities

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 11 September 2018 until 14 July 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 20. Certified since 26 September 2000

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10878.00

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

# Teleflex Medical

## ISO 13485:2016
## EN ISO 13485:2016

Issue 20

Detailed scope

**Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices. Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material. Manufacturing of sterile single use absorbable and non-absorbable sutures.**

**Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.**

Additional facilities

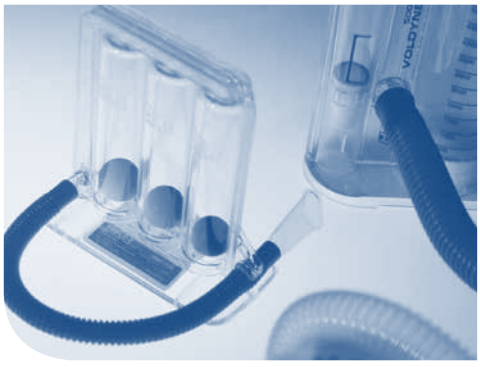
**375 Forbes Blvd, Mansfield, MA, 02048-1805, United States**

**2917 Weck Drive, Research Triangle Park, NC, 27709, United States**

UKAS MANAGEMENT SYSTEMS
0005

# HUDSON RESPIRATORY CARE

Oxygen Therapy, Aerosol Therapy, Incentive Spirometers



Teleflex

## TELEFLEX RESPIRATORY CARE PRODUCTS – A CLASS OF THEIR OWN

Trusted brands make Teleflex a reliable and strong partner. Built on a solid tradition of innovation, Teleflex is a global leader in superior medical supplies designed to help providers minimise risk and maximise outcomes for their patients. Our understanding of the importance to our customers of a full range of products has led to the development of a unique line of medical devices, all of which complement one another.

The HUDSON products for oxygen therapy, aerosol delivery and air entrainment presented to you in this brochure are not only in a class of their own but will help you manage the respiratory needs of your patients, while keeping an eye on quality, efficiency and cost. Our outstanding range of products features the broadest selection of masks, cannulas, tubing and humidifiers in the industry.

You can find further details and the technical specifications of our products within this brochure.

## TELEFLEX – HIGH QUALITY MEDICAL SUPPLIES FROM A SINGLE SOURCE



**LATEX-FREE**

*Teleflex is pleased to provide an extensive latex-free product offering. Natural latex rubber may possibly cause an allergic reaction.*

# OXYGEN THERAPY

## NONREBREATHING MASK
### WITH SAFETY VENT

- high concentration
- half open, low-resistance check valve prevents rebreathing and allows exhaled gas to escape
- flow rate: 5-10 LPM
- clear, soft vinyl
- latex-free
- clean
- single use
- individually packed

ADULT NONREBREATHING ELONGATED MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 1059 | with 210 cm of oxygen supply tubing | 50 |
| 41069 | without oxygen supply tubing | |

PAEDIATRIC NONREBREATHING ELONGATED MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41058 | with 210 cm of oxygen supply tubing | 50 |

## NONREBREATHING MASK

- high concentration
- closed, low-resistance check valve prevents rebreathing and allows exhaled gas to escape
- flow rate: 10-12 LPM
- clear, soft vinyl
- latex-free
- clean
- single use
- individually packed

ADULT NONREBREATHING ELONGATED MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41060 | with 210 cm of oxygen supply tubing | 50 |

MATERIALS
- mask: PVC with metal bracket
- tubing: PVC
- reservoir: PVC / 750 ml
- valve: silicone
- neck band: polycloroprene

# SEE-THRU® MASK

- medium concentration
- flow rate: 5-10 LPM
- clear, soft vinyl
- latex-free
- clean
- single use
- individually packed

### ADULT SEE-THRU MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41040 | with 210 cm of oxygen supply tubing | 50 |

### PAEDIATRIC SEE-THRU MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41035 | with 210 cm of oxygen supply tubing | 50 |

# SEE-THRU® MASK

- medium concentration
- flow rate: 5-10 LPM
- clear, soft vinyl
- latex-free
- clean
- single use
- individually packed

### ADULT SEE-THRU ELONGATED MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 1041 | with 210 cm of oxygen supply tubing | 50 |
| 1049 | without oxygen supply tubing | |

### PAEDIATRIC SEE-THRU ELONGATED MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41042 | with 210 cm of oxygen supply tubing | 50 |
| 41050 | without oxygen supply tubing | |

# SEE-THRU® MASK

- medium concentration
- flow rate: 5-10 LPM
- clear, soft vinyl
- adaptor swivels to accommodate patient position
- latex-free
- clean
- single use
- individually packed

### ADULT SEE-THRU ELONGATED MASK — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41007 | with 210 cm of oxygen supply tubing & reservoir | 50 |

**MATERIALS**
- mask: PVC with metal bracket
- tubing: PVC
- reservoir: PVC/750 ml
- neck band: polycloroprene

# 3-IN-1 MASK

3-in-1 masks can be used as a medium concentration, high concentration or nonrebreathing mask.

Each unit includes:
SEE-THRU mask with flapper valve, reservoir and oxygen connector

- high concentration
- flow rate: 5-10 LPM
- clear, soft vinyl
- latex-free
- clean
- single use
- individually packed

**MATERIALS**
- mask: PVC with metal bracket
- tubing: PVC
- reservoir: PVC / 750 ml
- connector: polypropylene
- neck band: polycloroprene

## ADULT 3-IN-1 ELONGATED MASK

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41061 | with 210 cm oxygen supply tubing | 50 |
| 41063 | with 210 cm STAR LUMEN tubing (kink-resistant) | |

# MULTI-VENT® MASKS
## VENTURI SYSTEMS

- features colour-coded, air-entrainment low and medium-concentration diluters
- includes adaptor for high humidity
- locking ring secures flow setting
- latex-free
- clean
- single use

*Low-concentration diluter (green) for 24%, 26%, 28% and 30%*

*Medium-concentration diluter (white) for 35%, 40% and 50%*

### ADULT MULTI-VENT ELONGATED MASK

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41088 | with 210 cm of oxygen supply tubing | 50 |

### PAEDIATRIC MULTI-VENT ELONGATED MASK

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41089 | with 210 cm of oxygen supply tubing | 50 |

MULTI-VENT Total Gas Flow to Patient*

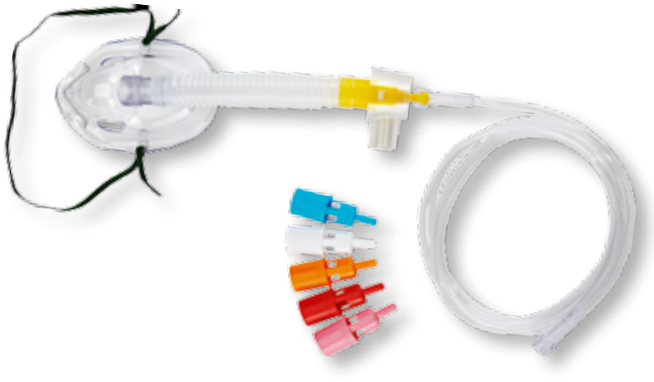
| OXYGEN % SETTING | SUGG. OXYGEN FLOW | TOTAL GAS FLOW |
|---|---|---|
| 24% | 3 LPM | 79 LPM |
| 26% | 3 LPM | 47 LPM |
| 28% | 6 LPM | 68 LPM |
| 30% | 6 LPM | 53 LPM |
| 35% | 9 LPM | 50 LPM |
| 40% | 12 LPM | 50 LPM |
| 50% | 15 LPM | 41 LPM |

* *At specific diluter and flow settings*

# SELECT-A-VENT® AIR ENTRAINMENT MASKS
## VENTURI SYSTEMS

Available as a kit (including six diluters: 24%, 28%, 31%, 35%, 40% and 50%) or as a single diluter.

- complete with 210 cm of oxygen tubing supply
- includes adaptor for high humidity
- latex-free
- clean
- single use



MATERIALS
- mask: PVC with metal bracket
- tubing: PVC
- connector: polypropylene
- neck band: polycloroprene

### ADULT SELECT-A-VENT AIR ENTRAINMENT ELONGATED MASKS

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41098 | kit with 210 cm of oxygen supply tubing | 50 |

# NASAL CANNULAS

## PATENTED NASAL CANNULAS WITH OPTIMAL PERFORMANCE

The curved nasal tips are thinner and softer to the touch and follow the anatomical contours of the patient's nose. The over-the-ear style cannulas are available in a variety of configurations offering the customer a choice of nasal tips, oxygen tubing, and tubing connectors.

- flow rate: 1-7 LPM
- latex-free
- clean
- single use

*Ref. 1103*

*Ref. 1104*

### ADULT OVER-THE-EAR NASAL CANNULAS

HUDSON RCI

| REF. | NASAL TIP | | TUBING | | | STANDARD TUBING CONNECTOR | QTY |
|---|---|---|---|---|---|---|---|
| | FLARED | NON-FLARED | STANDARD | STAR-LUMEN | LENGTH | | |
| 1103 | | x | x | | 210 cm | x | 50 |
| 1104 | x | | x | | 210 cm | x | |
| 41110 | | x | | x | 210 cm | x | |

# SOFTECH® NASAL CANNULAS

Extremely lightweight and flexible, the SOFTECH cannulas are anatomically designed to enhance patient acceptance and comfort. The over-the-ear style optimises fit and stability. Paediatric and infant sizes are also available.

- latex-free
- clean
- single use

HUDSON cannulas are available with either standard or universal hose end connectors. The universal connectors are convenient and economical because they attach directly to flow meters, thus eliminating the need for nipple-and-nut adaptors.

*Ref. 41820*

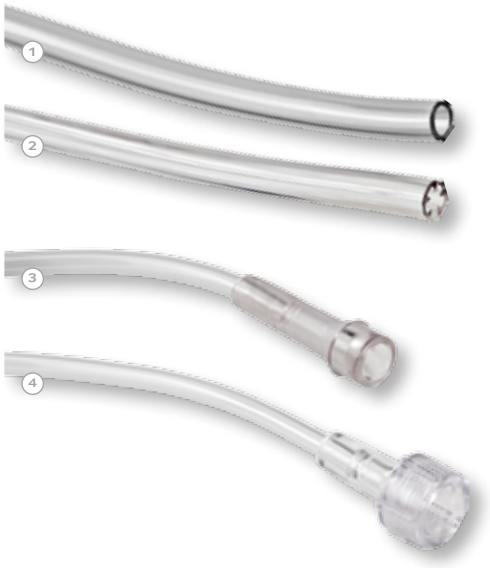
### SOFTECH NASAL CANNULAS

HUDSON RCI

| REF. | SIZE | TUBING | | TUBING CONNECTOR | | SUGGESTED FLOW RATE | QTY |
|---|---|---|---|---|---|---|---|
| | | STAR-LUMEN | LENGTH | STANDARD | UNIVERSAL | | |
| 41820 | Adult | x | 210 cm | x | | 4 LPM | 50 |
| 41826 | Paediatric | x | 210 cm | | x | 3.5 LPM | |
| 41828 | Infant | x | 210 cm | x | | 1.5-2 LPM | |

MATERIAL
- PVC

# OXYGEN SUPPLY TUBING




HUDSON offers both standard (fig. 1) and kink- and crush-resistant STAR LUMEN (fig. 2) tubing. The distinctively designed tubing features a 5-channel inner lumen for continuous oxygen flow.

HUDSON oxygen supply tubing is available with either standard (fig. 3) or universal hose end connectors (fig. 4). The universal connectors are convenient and economical because they attach directly to flow meters, thus eliminating the need for nipple-and-nut adaptors.

- latex-free
- clean
- single use

MATERIAL
- PVC

## OXYGEN SUPPLY TUBING

HUDSON RCI

| REF. | TUBING | | CONNECTOR | | LENGTH | QTY |
|---|---|---|---|---|---|---|
| | STANDARD | STAR-LUMEN | STANDARD | UNIVERSAL | | |
| 41113 | | x | x | | 210 cm | 50 |
| 1115 | x | | x | | 210 cm | 50 |
| 41118 | | x | x | | 420 cm | 50 |
| 41119 | | x | x | | 760 cm | 25 |
| 41120 | | x | x | | 1520 cm | 25 |
| 41925 | x | | | x | 210 cm | 50 |

# AQUAPAK®
## PREFILLED HUMIDIFIERS

HUDSON AQUAPAK® prefilled humidifiers combine an easy-to-use adaptor with a choice of two sterile water reservoir bottles. The humidifier adaptor incorporates an audible alarm that alerts the clinician to flow restriction or occlusion of the humidifier or oxygen tubing. The reservoir bottles have a built-in oxygen tubing connector with an easy snap-off trigger design. A micro-diffuser, moulded into the reservoir bottle, produces smaller bubbles and increases surface area agitation allowing for noise-free humidification. HUDSON AQUAPAK prefilled humidifiers provide performance, safety and value.
The complete set with its insufflation adaptor facilitates handling.

- latex-free
- gamma sterile
- single use
- individually packed

**MATERIALS**
- bottle: polypropylene
- adaptor: polycarbonate
- tubing: PVC
- valve: silicone

### AQUAPAK STERILE WATER, INCLUDES HUMIDIFIER ADAPTOR — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 400340 | 340 ml sterile aqua dest., includes Ref. 400040 sterile Humidifier Adaptor | 20 |
| 400640 | 650 ml sterile aqua dest., includes Ref. 400040 sterile Humidifier Adaptor | 10 |

### AQUAPAK STERILE WATER — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 400400 | 440 ml sterile aqua dest., water reservoir only, for use with Ref. 400011 Silent Adaptor | 20 |
| 403700 | 760 ml sterile aqua dest., water reservoir only, for use with Ref. 400011 Silent Adaptor | 10 |

### AQUAPAK® STERILE WATER, WITHOUT HUMIDIFIER ADAPTOR — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 400301 | 340 ml sterile aqua dest., water reservoir only, for use with Ref. 400040 Humidifier Adaptor | 20 |
| 400601 | 650 ml sterile aqua dest., water reservoir only, for use with Ref. 400040 Humidifier Adaptor | 10 |

### AQUAPAK SILENT ADAPTOR — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 400011  | • no bubbles, vibration or noise<br>• pressure relief valve, 140-210 cm $H_2O$<br>• audible pop-off<br>• designed for use with Ref. 400400 or 403700 sterile water<br>• optional external heater capability for use with Ref. 050-12 AQUATHERM series heaters<br>• single use | 50 |

### HUMIDIFIER ADAPTOR — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 400040  | • sterile, clear adaptor body for use with Ref. 400301 or Ref. 400601<br>• pressure relief valve 350-700 cm $H_2O$<br>• audible pop-off<br>• single use | 120 |

# DISPOSABLE HUMIDIFIER

HUDSON offers a choice of humidifiers that can be used with the clinician's water source. Available in disposable form, these humidifiers incorporate an audible pressure-relief valve to signal occlusion of the humidifier or oxygen tubing.

- disposable, durable plastic with preset audible alarm at 280 cm $H_2O$ (4 psi) pressure relief
- defined minimum and maximum water level lines
- latex-free
- single use
- individually packed

MATERIALS
- housing: polyethelene
- adaptor: polypropylene
- pressure compensation valve: silicone

| DISPOSABLE HUMIDIFIER | | HUDSON RCI |
|---|---|---|
| REF. | FILLING VOLUME | QTY |
| 3230 | 500 ml | 50 |

# ACCESSORIES

## NIPPLE AND NUT

HUDSON RCI

| | REF. | DESCRIPTION | QTY |
|---|---|---|---|
|  | 42555 | barbed hose adaptor for standard D.I.S.S. threaded oxygen outlets<br>• latex-free<br>• clean<br>• single use | 50 |

## OXYGEN SUPPLY TUBING CONNECTOR

HUDSON RCI

| | REF. | DESCRIPTION | QTY |
|---|---|---|---|
|  | 41420 | couples oxygen supply tubing utilising 5 to 7 mm end connectors<br>• latex-free<br>• clean<br>• single use | 250 |

## OXYGEN TUBING WATER TRAP

HUDSON RCI

| | REF. | | QTY |
|---|---|---|---|
|  | 1679 | • latex-free<br>• clean<br>• single use | 10 |

## TUBING ADAPTOR

HUDSON RCI

| | REF. | DESCRIPTION | QTY |
|---|---|---|---|
|  | 1423 | 22 mm ID x 5 - 7 mm (taper)<br>• latex-free<br>• clean<br>• single use | 50 |

## TRACH TEE OXYGENATOR

HUDSON RCI

| | REF. | DESCRIPTION | QTY |
|---|---|---|---|
|  | 41668 | includes oxygen nipple adaptor, aerosol tee and CORR-A-FLEX tube<br>• latex-free<br>• clean<br>• single use | 50 |

# AEROSOL THERAPY

## MICRO MIST® SMALL VOLUME NEBULISER

The MICRO MIST small volume nebuliser is designed for performance and economy and can be used for hand-held or in-line treatments. The MICRO MIST produces a fine, dense mist at angles up to 90°, with optimal particle size, efficient nebulisation rates and minimal residuals. An easy-seal, threaded cap and 6 ml capacity anti-spill jar prevent leakage and ensure easy assembly/disassembly.

- latex-free
- clean
- single use

**MATERIALS**
- aerosol mask: PVC
- housing: polystyrene
- tee: K-resin
- valve: polyisoprene

**ATTENTION**
do not use with oily medications

Due to its innovative capillary design, the MICRO MIST small volume nebuliser can deliver a fine, dense mist at any angle up to 90°. This allows the clinician to administer medications to patients with special treatment requirements such as those who are positioned horizontally.

### MICRO MIST SMALL VOLUME NEBULISER

HUDSON RCI

| REF. | MICRO MIST NEBULISER | TEE | MOUTHPIECE | 15 CM RESERVOIR TUBING | 210 CM TUBING | STANDARD TUBING CONNECTOR | UNIVERSAL TUBING CONNECTOR | ADULT MASK REF. 1083 | PAEDIATRIC MASK REF. 41085 | QTY |
|---|---|---|---|---|---|---|---|---|---|---|
| |  |  |  |  |  |  |  |  |  | |
| 41880* | x | | | | | | | | | 50 |
| 41883* | x | x | x | x | x | x | | | | |
| 41890 | x | | | | | | | | | |
| 41891 | x | x | | | x | x | | | | |
| 41892 | x | x | x | | x | x | | | | |
| 41893 | x | | | | x | x | | x | | |
| 41894 | x | | | | x | x | | | x | |
| 41895 | x | x | x | x | x | | x | | | |
| 41898 | x | | | | x | | x | x | | |

* *Ref. 41883 and Ref. 41880 have 18 mm cap and tee. All others have 22 mm connectors.*

### MICRO MIST HOLDER

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 90930 | for secure fixation of the complete system before or after treatment | 1 |

# MICRO MIST® NEBULISER WITH IN-LINE NEB-TEE™ WITH VALVE

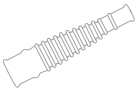
The MICRO MIST nebuliser with Neb-Tee has an in-built spring-loaded self-opening and closing valve, that allows treatment delivery without opening the circuit or interrupting ventilation. Neb-Tee with 22 mm ID – 22 mm OD connectors.

- latex-free
- clean
- single use

The Neb-Tee is designed to simplify access to 22 mm ventilator circuits for small volume nebuliser treatments.

## MICRO MIST NEBULISER WITH IN-LINE NEB-TEE WITH VALVE

HUDSON RCI

| REF. | MICRO MIST NEBULISER | NEB-TEE | FLEXTUBE 22 F/15 F | 210 CM TUBING | STANDARD TUBING CONNECTOR | QTY |
|---|---|---|---|---|---|---|
| |  |  |  |  |  | |
| 41745 | x | x | x | x | x | 50 |

**MATERIALS**
- aerosol mask: PVC
- housing: polyisoprene
- tee: K-resin
- valve: polyisoprene

**ATTENTION**
do not use with oily medications

- recommended mimimum volume: 1 ml
- recommended flow rate: 8 LPM
- MMAD (Mass Median Aerodynamic Diameter): 2.7 microns
- nebulisation rate: 0.34 ml/min
- volume of nebulisation jar: 6 ml

# UP-DRAFT® II NEBULISER

The compact, high output UP-DRAFT II produces a concentrated mist at flow rates of 5-9 LPM. It nebulises at angles up to 45° to accommodate special treatment requirements. An easy-seal, threaded cap and 8 ml capacity scalloped skirt anti-spill jar prevent leakage and ensure easy assembly/disassembly. The UP-DRAFT II offers exceptional mist, therapeutic particle size, and efficient nebulisation times.

- latex-free
- clean
- single use

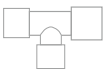
**MATERIALS**
- aerosol mask: PVC with metal bracket
- housing: polystyrene
- tubing: PVC
- tee: K-resin

**ATTENTION**
do not use with oily medications

recommended flow rate: 5-9 LPM
MMAD: 2-3 microns
nebulisation rate: 0.2-0.3 ml/min.
volume: 8 ml

## UP-DRAFT II NEBULISER

HUDSON RCI

| REF. | UP-DRAFT II NEBULISER | TEE | MOUTHPIECE | 15 CM RESERVOIR TUBING | 210 CM TUBING | ADULT MASK REF. 1083 | PAEDIATRIC MASK REF. 41085 | QTY |
|---|---|---|---|---|---|---|---|---|
| |  |  |  |  |  |  |  | |
| 41705 | x | | | | x | x | | 50 |
| 41707 | x | | | | x | | x | |
| 41730 | x | | | | | | | |
| 41732 | x | x | x | | x | | | |
| 1734 | x | x | x | x | x | | | |

# UP-DRAFT® NEBULISER

The UP-DRAFT nebuliser is ideal for hospital or home care settings where its size, design and performance make it especially suitable. A screw-on lid forms a leak-proof seal and is easy to assemble/disassemble. The large-capacity, free-standing jar (5-15 ml) with its clearly marked maximum fill line and the low-resistance jet orifice is especially suitable for use with larger amounts of liquid.

- latex-free
- clean
- single use

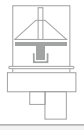
**MATERIALS**
- aerosol mask: PVC with metal bracket
- housing: polystyrene
- tubing: PVC
- tee: K-resin

**ATTENTION**
do not use with oily medications

recommended flow rate: 5-9 LPM
MMAD: 2-3 microns
nebulisation rate: 0.2-0.3 ml/min.
volume: 15 ml

## UP-DRAFT NEBULISER

HUDSON RCI

| REF. | UP-DRAFT NEBULISER | TEE | MOUTHPIECE | 210 CM TUBING | ADULT MASK REF. 1084 | ADULT MASK, REF. 1083 (UNDER CHIN) | QTY |
|---|---|---|---|---|---|---|---|
| |  |  |  |  |  |  | |
| 41700 | x | | | | | | 50 |
| 41710 | x | | | x | | x | |
| 41712 | x | | | x | x | | |
| 41720 | x | x | x | x | | | |

# ISO-NEB® PENTAMIDINE NEBULISATION SET WITH FILTER

The ISO-NEB filtered nebuliser system was designed to reduce environmental contamination during aerosol therapy. Inspiratory and expiratory flow are isolated by one-way valves with exhalation directed through an efficient filter system. The electrostatically charged pathogen filter, with a 99.999%/99.99% bacterial/viral filtration rating, protects staff and environment from spray residue. The system incorporates the UP-DRAFT II, which is a high-output, 8 ml, small-volume nebuliser that operates vertically or at an angle up to 45°. Individually packed.

- latex-free

recommended flow rate: 5-9 LPM
MMAD: 2-3 microns
nebulisation rate: 0.2-0.3 ml/min.
volume: 8 ml

ISO-NEB PENTAMIDINE NEBULISATION SET — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41755 | with filter | 20 |

# SIDE DRAFT NEB-U-MIST NEBULISER

- ”Side-Draft” style small volume nebuliser
- nebuliser with tee and mouthpiece
- latex-free

SIDE DRAFT NEB-U-MIST NEBULISER — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41897 | with tee and mouthpiece | 50 |

# AQUAPAK®
## PREFILLED NEBULISERS

AQUAPAK prefilled nebulisers offer versatile, sterile systems to provide cold or heated nebulisation. Choose from a wide variety of reservoirs, adaptors and solutions to meet specific patient requirements efficiently and economically.

- latex-free
- gamma sterile

### NEBULISER ADAPTOR 028 — HUDSON RCI

| REF. | | DESCRIPTION | QTY |
|---|---|---|---|
| 403128 |  | • Venturi-style entrainment ring allows the selection of oxygen concentrations from 28% to 98%<br>• adaptor: polycarbonate<br>• individually packed<br>• sterile | 50 |

### NEBULISER ADAPTOR 033 — HUDSON RCI

| REF. | | DESCRIPTION | QTY |
|---|---|---|---|
| 403133 |  | • quiet adaptor allows the selection of oxygen concentrations from 33% to 98% to meet the needs of the ICU patient<br>• adaptor: polycarbonate<br>• individually packed<br>• sterile | 50 |

- select between two AQUAPAK precision nebuliser adaptors for delivery of a consistent aerosol over a wide range of oxygen concentrations
- AQUATHERM III heater provides heated aerosol treatment
- prefilled AQUAPAK sterile reservoirs are available in four convenient sizes: 440 ml, 760 ml, 1070 ml, and 2200 ml
- available with both reservoir and sterile adaptor conveniently packed together
- AQUAPAK reservoir may be used with other HUDSON humidification and nebulisation products, making the system truly versatile

### CLOSED STERILE WATER SYSTEM FOR MECHANICAL NEBULISATION + ADAPTOR — HUDSON RCI

| REF. | 440 ML | 760 ML | 1070 ML | 2200 ML | STERILE WATER | 0.45% SALINE | 0.9% SALINE | ADAPTOR 028 | ADAPTOR 033 | QTY |
|---|---|---|---|---|---|---|---|---|---|---|
| 400400 | x | | | | x | | | | | 20 |
| 403128 | | | | | | | | x | | 50 |
| 403133 | | | | | | | | | x | 50 |
| 403700 | | x | | | x | | | | | 10 |
| 403705 | | x | | | | x | | | | 10 |
| 403709 | | x | | | | | x | | | 10 |
| 403728 | | x | | | x | | | x | | 10 |
| 404000 | | | x | | x | | | | | 10 |
| 404128 | | | x | | x | | | x | | 10 |
| 404200 | | | | x | x | | | | | 4 |
| 404290 | | | | x | | | x | | | 4 |
| 404428 | x | | | | x | | | x | | 20 |
| 404739 | | | | x | | | x | x | | 4 |

# DISPOSABLE LARGE VOLUME NEBULISER FOR MECHANICAL VENTILATION

- 500 ml
- defined maximum and minimum water level lines
- concentration: 28%-98%
- latex-free
- single use
- individually packed

**MATERIALS**
- housing: polyethylene
- adaptor: polycarbonate

DISPOSABLE LARGE VOLUME NEBULISER FOR MECHANICAL VENTILATION — HUDSON RCI

| REF. | QTY |
|---|---|
| 41770 | 50 |

# AQUATHERM® III EXTERNAL ADJUSTABLE ELECTRONIC HEATER

- attaches onto the nebuliser system to provide heated aerosol
- adjustable aerosol temperature to meet patient needs with a sensitive temperature controller
- robust, durable heater

AQUATHERM III EXTERNAL ADJUSTABLE ELECTRONIC HEATER — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 050-12 D | 220 - 240 V, 50 Hz | 1 |
| 050-12 E | United Kingdom style power plug | |

# TRACHEOSTOMY MASK

- for tracheostomy and laryngectomy aerosol therapy
- tubing connector swivels 360° and accepts 22 mm I.D. corrugated tubing
- clean
- single use
- individually packed

**MATERIALS**
- mask: PV with metal bracket
- adaptor: polyethylene
- neck band: polycloroprene

| TRACHEOSTOMY MASK | HUDSON RCI | |
|---|---|---|
| REF. | DESCRIPTION | QTY |
| 1075 | with adult size mask | 50 |
| 41076 | with paediatric size mask | |

# AEROSOL MASK

- clear, soft vinyl
- specifically designed for aerosol therapy
- connector accepts 22 mm aerosol tubing
- clean
- single use
- individually packed

| ELONGATED AEROSOL MASK | HUDSON RCI | |
|---|---|---|
| REF. | DESCRIPTION | QTY |
| 1083 | with adult size mask | 50 |
| 41085 | with paediatric size mask | |

# FACE TENT

- clear, soft vinyl
- for high-humidity aerosol therapy
- connector accepts 22 mm aerosol tubing
- clean
- single use
- individually packed

| FACE TENT | HUDSON RCI | |
|---|---|---|
| REF. | | QTY |
| 41095 | | 50 |

# CORR-A-FLEX® II ROLL TUBING

- 30.4 m roll of CORR-A-FLEX II tubing, PVC
- extremely lightweight and flexible
- with cuttable sections every 15 cm
- for heated and nonheated therapy applications
- tubing ends have a collar which slips on and locks securely to 22 mm adaptors
- latex-free


CORR-A-FLEX II ROLL TUBING — HUDSON RCI

| REF. | QTY |
|---|---|
| 1680 | 1 roll |

# AEROSOL DRAINAGE SYSTEM

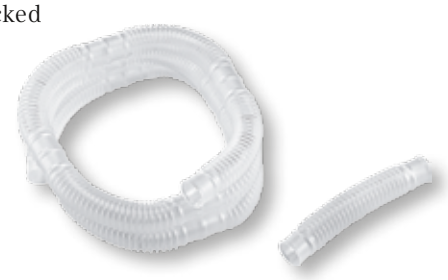
- disposable drainage bag with a tee adaptor which accepts standard 22 mm I.D. corrugated tubing
- self-locking plastic chain secures bag to a stable object
- convenient drainage port
- material: tee polyethylene, bag PVC
- clean
- single use

AEROSOL DRAINAGE SYSTEM — HUDSON RCI

| REF. | BAG CAPACITY | QTY |
|---|---|---|
| 41740 | 750 ml | 50 |

# CORR-A-FLEX® TUBE

- exceptionally flexible, lightweight tubing, PVC
- length 180 cm
- with cuttable sections every 15 cm
- collared tubing end slips on and locks to 22 mm adaptors for secure fit
- latex-free
- individually packed



CORR-A-FLEX TUBE — HUDSON RCI

| REF. | QTY |
|---|---|
| 41518 | 50 |

# ADDIPAK® UNIT DOSE

- 3 ml and 5 ml vials of sterile 0.9% saline solution for inhalation therapy
- inverted millilitre graduations for accurate dispensing

ADDIPAK UNIT DOSE — HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 200-39 | 0.9% - full normal saline, 3 ml (pink vial) | 100 |
| 200-59 | 0.9% - full normal saline, 5 ml (pink vial) | |

# ACCESSORIES

## AEROSOL TEE CONNECTOR

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41077  | • anti-spill design minimises aspiration of liquids<br>• horizontal axis: 22 mm O.D.<br>• vertical axis: 15/22 mm O.D.<br>• polycarbonate<br>• latex-free<br>• clean<br>• single use | 50 |

## MOUTHPIECE

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41565  | • standard mouthpiece with 15 mm and 22 mm O.D. connections<br>• polyethylene<br>• latex-free<br>• clean<br>• single use | 50 |

## NEBULISER TEE CONNECTOR

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41639  | • standard 22 mm I.D./O.D. connect.<br>• nebuliser port is 18 mm I.D. connection, fits most small volume nebulisers<br>• polyethylene<br>• latex-free<br>• clean<br>• single use | 50 |

## NEBULISER TEE CONNECTOR

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41651  | • 22M/15F - 22M/22F<br>• with Anti-Spill design<br>• polycarbonate<br>• latex-free<br>• clean<br>• single use | 50 |

## ONE-WAY VALVE

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41664  | • valve offers low-flow resistance in one direction<br>• 22 mm O.D./22 mm I.D. connection<br>• polycarbonate/silicone<br>• latex-free<br>• clean<br>• single use | 50 |

## ONE-WAY VALVE

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41665  | • valve offers low-flow resistance in one direction<br>• 22 mm O.D./22 mm I.D. connection<br>• polycarbonate/silicone<br>• latex-free<br>• clean<br>• single use | 50 |

## UNIDIRECTIONAL VALVED TEE

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41666  | • assembled tee and two one-way valves, gas flow in one direction only<br>• 22 mm O.D./22 mm I.D. connection<br>• polycarbonate/silicone<br>• latex-free<br>• clean<br>• single use | 50 |

## MDI ADAPTOR

HUDSON RCI

| REF. | DESCRIPTION | QTY |
|---|---|---|
| 41659  | • with integrated aerosol port<br>• standard 22 mm I.D./O.D. connections for placement in-line<br>• tee adaptor with arrow allows clinician to direct aerosolised medication toward patient or away for “reservoir” effect<br>• for all standard sprays<br>• fits most standard MDI canisters<br>• polyethylene<br>• latex-free<br>• clean<br>• single use | 50 |

# INCENTIVE SPIROMETERS

**THE EFFECTIVE BREATHING THERAPY WITH SUSTAINED MAXIMAL INSPIRATION**

The incentive spirometers from HUDSON visualise patients' breathing performance (ball, markings) and thus induce them to take deeper and longer breaths. Since they do not need to be reprocessed, these single-patient products are also very economical.

## TRIFLO® II

- flow-oriented, 3-ball incentive spirometer with mouthpiece and tubing
- three colour-coded balls/three chambers
- minimum flow imprinted on each chamber
- compact design and break-resistant plastic
- latex-free

TRIFLO II — HUDSON RCI

| REF. | FLOW RATE | SIZE | QTY |
|---|---|---|---|
| 8884717395 | 600-1200 ml/sec. | housing (length/width/height) 13.5/7/14 cm<br>tubing 28 cm long<br>mouthpiece 6.5 cm long | 12 |

## VOLDYNE®

- volume-oriented incentive spirometer with mouthpiece and tubing
- two sizes to cater for small as well as large inspired volumes
- compact, economical design with built-in handle
- markings on both sides
- latex-free


*Ref. 8884719041*

VOLDYNE 2500/VOLDYNE 5000 — HUDSON RCI

| REF. | DESCRIPTION | VOLUME MEASUREMENT | SIZE | QTY |
|---|---|---|---|---|
| 8884719041 | Voldyne 2500 for adult and paediatric use | 250 ml to 2500 ml | housing (length/width/height) 13.5/7/14 cm<br>tubing 28 cm long<br>mouthpiece 6.5 cm long | 12 |
| 8884719033 | Voldyne 5000 for adult use | 250 ml to 5000 ml | housing (length/width/height) 13.5/7/14 cm<br>tubing 28 cm long<br>mouthpiece 6.5 cm long | |

# LUNG VOLUME EXERCISER

- flow-oriented incentive spirometer with mouthpiece and tubing
- dual-chamber design creates a constant resistance for deep and prolonged inspiration
- break-resistant material
- latex-free

## LUNG VOLUME EXERCISER FOR ADULT AND PAEDIATRIC USE

HUDSON RCI

| REF. | FLOW RATE | QTY |
|---|---|---|
| 41750 | 200-1200 ml/sec. (adjustable flow settings) | 10 |

Teleflex is a leading global provider of specialty medical devices used for diagnostic and therapeutic procedures in critical care, urology and surgery. Our mission is to provide solutions that enable healthcare providers to improve outcomes and enhance patient and provider safety.
We specialise in devices for general and regional anaesthesia, cardiac care, respiratory care, urology, vascular access and surgery and we serve healthcare providers in more than 150 countries. Teleflex also provides specialty products for medical device manufacturers.



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Teleflex

# Bouffant Caps

Non sterile

# TECHNICAL DATA SHEET

CE

## Description

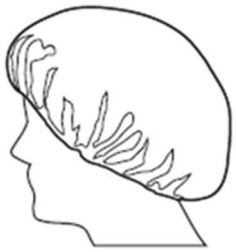
*Reference*
69801: Bouffant Cap, Blue, Large, Non-Sterile
69803: Bouffant Cap, Blue, X-Large, Non-Sterile

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

*Dimensions*

| | ***L*** | ***XL*** |
|---|---|---|
| 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$^2$



## 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.


*Created 31-Mar-2015, version 0*


*The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.*