MAKERS OF RESPIRATORY VALVES SINCE 1938

HANS RUDOLPH, inc. **8325 Cole Parkway ■ Shawnee, KS 66227 USA**

PH: (913) 422-7788 USA & Canada: (800) 456-6695 FAX: (913) 422-3337 hri@rudolphkc.com
ISO 9001:2008 ISO 13485:2003 www.rudolphkc.com

Quality Management System

Quality Management System (QMS) is certified to the following Standards:
ISO 9001, ISO 13485 (CMDCAS program Health Canada) through BSI. HRI has a CE Certificate through BSI for Full Quality Assurance Approval per Annex II of the EC Council Directive 93/42/EEC, certificate CE 598572. HRI's QMS also meets the U.S.A. FDA (Food & Drug Administration) Good Manufacturing Practices- Quality System Regulation (GMP-QSR), including the FDA-MDR (Medical Device Reporting), the European Commission "Medical Devices Vigilance System", and the Canadian MDR Medical Devices Regulations SOR/98-282.

EU Authorize Representative is:
M. Devices Group (Medical Devices Group):
Medical Devices Group
Marlborough House, Riding Street
Southport
PR8 1 EW, England

Tel: +44 1704 544 944
Fax: +44 1704 544 050

Hans Rudolph, inc. QMS uses controlled documents, which are employed as the Quality Assurance Manual, Operating Procedures, Work Instructions and Tests Methods.

Best Regards,

Lee A Stroh

Lee A. Stroh **September 21, 2016**
Quality Assurance Manager
Management Representative

791281-06 DCN: 29349

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2008

This is to certify that:

Hans Rudolph, inc.
8325 Cole Parkway
Shawnee
Kansas
66227
USA

Holds Certificate No: **FM 598076**

and operates a Quality Management System which complies with the requirements of ISO 9001:2008 for the following scope:

The designer, manufacturer, and distributor of respiratory valves, directional control valves, face and nasal masks, pneumotachometer, volumetric calibration syringes, calibration gases, and respiratory accessories, for hospitals, universities, and original equipment manufacturers.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 05/28/2013
Latest Revision Date: 08/05/2016

Effective Date: 11/19/2016
Expiry Date: 09/14/2018

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Hans Rudolph, inc.
8325 Cole Parkway
Shawnee
Kansas
66227
USA

Holds Certificate No: **FM 598075**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

FM 598075 The designer, manufacturer, and distributor of respiratory valves, directional control valves, face and nasal masks, pneumotachometer, volumetric calibration syringes, calibration gases, and respiratory accessories, for hospitals, universities, and original equipment manufacturers.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 05/28/2013 Effective Date: 08/05/2016 Expiry Date: 02/28/2019

CMDCAS Recognized Registrar

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 598572**

Issued To: **Hans Rudolph, inc.**
8325 Cole Parkway
Shawnee
Kansas
66227
USA

In respect of:

The design, development and manufacture of respiratory valves, masks, connectors, gas bags and pneumotachometers

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **05 July 2013** Date: **09 September 2014** Expiry Date: **09 September 2019**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 598572**
Date:	**09 September 2014**
Issued To:	**Hans Rudolph, inc.** **8325 Cole Parkway** **Shawnee** **Kansas** **66227** **USA**

Subcontractor:	**Service(s) supplied**
M. Devices Group (Medical Devices Group) Marlborough House Riding Street Southport PR8 1EW United Kingdom	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 598572**

Date: **09 September 2014**

Issued To: **Hans Rudolph, inc.**
8325 Cole Parkway
Shawnee
Kansas
66227
USA

Date	Reference Number	Action
05 July 2013	7984855	First issue. Transfer from another Notified Body
09 September 2014	8215131	Certificate renewal

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