

Certificate of Registration



Certificate Number
99-1442h

Initial Certification Date
May 5, 1999

Certificate Issue Date
November 18, 2010

Certificate Expiry Date
November 18, 2013



The following organization's quality management system has been assessed and registered by Intertek Testing Services NA, Inc. as conforming to the requirements of:

ISO 9001:2008

Organization:

Hans Rudolph, Inc.

8325 Cole Parkway, Shawnee, Kansas, 66227, USA

The Quality Management System is applicable to:

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

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement.

A handwritten signature in black ink, appearing to read 'K. Miral'.

Intertek Testing Services NA, Inc. – Boxborough, MA, USA

Certificate of Registration



Certificate Number
9016-4

Initial Certification Date
May 15, 2001

Certificate Effective Date
November 18, 2010

Certificate Expiry Date
November 18, 2013



The following organization's quality management system has been assessed and registered by Intertek Testing Services NA Ltd., a **CMDCAS recognized registrar**, as conforming to the requirements of:

ISO 13485:2003

Organization:

Hans Rudolph, Inc.

8325 Cole Parkway, Shawnee, Kansas, 66227, USA

The Quality Management System is applicable to:

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

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement.



David S. Muil – General Manager - Canada
Intertek Testing Services NA Ltd. – Lachine, QC, Canada

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41313309

Initial Certification Date
September 9, 1999

Certificate Valid from
September 9, 2009

Certificate Expiry Date
September 9, 2014

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

*Intertek Semko AB
Box 1103, SE-164 22 Kista,
Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com*

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Hans Rudolph, Inc

8325 Cole Parkway, Shawnee, KS 66227, USA

Product Category:

Respiratory valves, masks, connectors, gas bags and pneumotachometers.
Class IIa

For further identification of the products covered, see the MDD product list/product schedule.

August 11, 2009

Signed date



Marie Olsson, Certification Manager MDD
Intertek Semko AB, Kista, Sweden