

# 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 non-sterile 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-07-05**

Date: **2019-09-06**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 598572

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Number	Device name	Intended purpose
Class IIa		
MD 0101	One Way Respiratory Valves	N/A
MD 0101	Two Way Non-Rebreathing Valve	
MD 0101	Inflatable Balloon-Type Valves	
MD 0101	Mouthpieces	
MD 0101	Face Mask with Two-Way Valves	
MD 0101	Respiratory Connectors Accessory	
MD 0106	Manual and Pneumatic Valves	
MD 0106	Linear Pneumotachometer	
MD 0106	Non-Diffusing Gas Bag	
MD 0101	Oro-Nasal Masks	

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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.

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## List of Significant Subcontractors

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

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**Shawnee**  
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**66227**  
**USA**

**Subcontractor:**

**Service(s) supplied**

E C Rep Ltd.  
5 Fitzwilliam Square East  
Dublin 2  
DO2 R744  
Ireland

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 598572**  
 Date: **2019-09-06**  
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 USA**

Date	Reference Number	Action
05 July 2013	7984855	First issue. Transfer from another Notified Body.
09 September 2014	8215131	Certificate renewal.
24 January 2019	8901991	Traceable to NB 0086.
Current	9788297	Certificate renewal. Change of certificate scope to include "non-sterile". Change of details for EU Representative.