



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 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.

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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## Supplementary Information to CE 598572

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**USA**

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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