



**HANS RUDOLPH, inc.**  
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## **EC DECLARATION OF CONFORMITY**

### **Council Directive 93/42/EEC Annex II, Section 3.2**

### **On Medical Devices**

Manufacture's Name: HANS RUDOLPH, inc.  
Manufacture's Address: 8325 Cole Parkway, Shawnee KS 66227 USA

Type of Equipment: Oro-Nasal NIV Mask  
Product Series (Model Number): 7500

Classification: IIa

EC Certificate CE 598572

Notified Body: BSI

Identification Number: 2797

Rule(s) used for Classification: 2

Harmonized Standards to which Conformity is Declared: ISO 5356-1:2015,  
BS EN ISO 15223-1:2016, EN 1041:2008 + A1:2013, AAMI/ISO 10993-1:2009/(R)2013,  
ISO 10993-10:2013, ISO 10993-3:2014

Approved By: \_\_\_\_\_

**Kevin Rudolph**  
**CEO of Hans Rudolph, inc.**

Date: \_\_\_\_\_

MAY 13, 2019