



HANS RUDOLPH, inc.
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Authorized Representative in EU:

EC	REP
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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: 0086

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:

AVG 22, 2017