standard neonate/infant circuit with neonate / infant nasal prongs replacing the wye (Figure 12). Use of a proximal pressure line with the eVolution ventilators is not required when using nasal prong interfaces. NCPAP+ mode is appropriate for use with most nasal prong systems as shown below.

Argyle Infant Nasal Prongs
nasal prong systems that attach to a circuit wye

F&P Infant Nasal Prongs

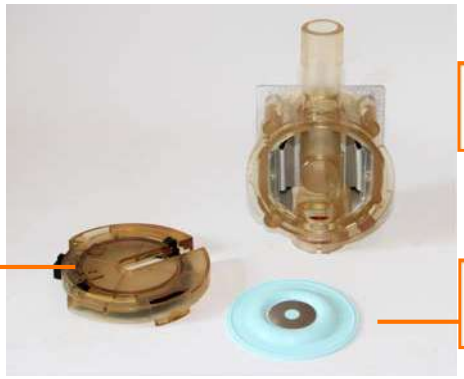
INCA Infant Nasal Prongs

Hudson Infant Nasal Prongs

Figure 12: NCPAP Prongs

Attach the nasal prong interface to the circuit as required. Cap or close any open pressure ports on the nasal prong interface as the eVolution NCPAP+ mode does not require use of a proximal pressure line.

2.11.2 Exhalation System



EC Certificate Full Quality Assurance System: Certificate US19/819943514

The management system of

eVent Medical Ltd

60 Empire Drive,
Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

INSPIRATION™ ventilators for continuous respiratory support in an acute and sub-acute institutional healthcare environment, EVOLUTION™ ventilators for continuous ventilation for patients requiring respiratory support.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 10 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 05 October 2000
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MW 201252

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Authorised by

Pieter Weterings
Certification Manager

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SGS House Noorderlaan 87 2030 Antwerp Belgium
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Certificate US00/52067

The management system of

eVent Medical Ltd

60 Empire Drive,
Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture, servicing and distribution of INSPIRATION™ LS, 5i, and 7i ventilators and EVOLUTION™ 3e ventilators.

This certificate is valid from 10 February 2021 until 10 February 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 February 2024
Issue 18. Certified since 05 October 2000

Authorised by

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