

Declaration of Conformity

Application of Council Directive(s): Medical Device Directive 93/42/EEC including Amendments

Manufacturer's Name: CareFusion

Manufacturer's Address: 22745 Savi Ranch Parkway
Yorba Linda, CA, 92887 USA

EU Notified Body: B.S.I. Product Services (Reg. No. 0086)

European Authorized Representative: CareFusion 234 GmbH
Leibnizstraße 7
97204 Hoechberg, Germany

Conformity Assessment: MDD Annex II

Quality System: ISO 13485: 2003

Type of Equipment: Breathing Circuits and Masks

Trade name: Infant Flow LP

Model Numbers See Page 2

Device Classification: Class IIa, Rule 11 of Annex IX

CE Certificate CE 00663

Note:

- a) CareFusion has verified the, mutual compatibility of the devices in this kit in accordance with the manufacturers' instructions and have carried out their operations in accordance with their instructions; and
- b) CareFusion has packaged the system pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- c) The whole activity is subjected to appropriate methods of internal control and inspection.

CareFusion hereby declares that the equipment specified above conforms to the above Directive.

Place: Yorba Linda, CA USA

Date: 2014-01-24


(Signature)

Donald Sherratt
(Full Name)

Director, Regulatory Affairs & Compliance
(Position/Title)



Infant Flow LP Components

	Part Number	Description	Classification	Kit Assembler
1	7772020LP	Infant Flow LP Generator Kit includes generator, sizing guide, and small, medium, and large nasal prongs; Single Patient Use. Box of 10	Class IIa, Rule 11 of Annex IX	CareFusion*
2	7772000LP	Infant Flow LP Generator Kit without prongs.	Class IIa, Rule 11 of Annex IX	CareFusion*
3	7772010	Infant Flow LP Starter Kit includes 5 generator kits, 2 of each size of Infant Flow LP nasal mask, 2 of each size of Infant Flow LP headgear, 2 extra small, and 2 extra large prongs. Box of 1	Class IIa, Rule 11 of Annex IX	CareFusion*
4	7772011	Infant Flow LP generator and F&P RT132 neonatal single-limb, heated circuit; Single Patient Use. Box of 10. Fisher& Paykel MR730 & MR850 humidifiers.	Class IIa, Rule 11 of Annex IX	CareFusion*
5	7772021	Infant Flow LP generator and F&P RT132 neonatal single-limb, heated circuit; Single Patient Use. Box of 20. Fisher& Paykel MR730 & MR850 humidifiers.	Class IIa, Rule 11 of Annex IX	CareFusion*

***Note:**

Infant Flow LP Kits:

Kit Components	Manufacturer	Country of Origin	Class	CE Marking
Circuits	Fisher & Paykel	New Zealand	IIa	CE 0123
Generator	CareFusion	Mexico	IIa	CE 0086
Nasal masks	CareFusion	USA	IIa	CE 0086
Nasal prongs	CareFusion	USA	IIa	CE 0086
Bonnets	A Plus International (Suzhou Avon International Textile Co.) - China	China	I	CE
Headgear	Productos Urologos De Mexico S.A. De C.V.	Mexico	I	CE