

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: Nasal Prongs and Nasal Masks

Trade name: Infant Flow LP

Model Numbers See Page 2

Device Classification: Class IIa, Rule 11 of Annex IX

CE Certificate CE 00663

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

Place: Yorba Linda, CA USA

Date: 2014-02-05


(Signature)

Donald Sherratt
(Full Name)

Director, Regulatory Affairs & Compliance
(Position/Title)



Infant Flow LP Components

	Part Number	Description	Classification
1	777000XS	Infant Flow LP nasal prong, Single Patient Use; Extra Small. Box of 10	Class IIa, Rule 11 of Annex IX
2	777000S	Infant Flow LP nasal prong, Single Patient Use; Small. Box of 10	Class IIa, Rule 11 of Annex IX
3	777000M	Infant Flow LP nasal prong, Single Patient Use; Medium. Box of 10	Class IIa, Rule 11 of Annex IX
4	777000L	Infant Flow LP nasal prong, Single Patient Use; Large. Box of 10	Class IIa, Rule 11 of Annex IX
5	777000XL	Infant Flow LP nasal prong, Single Patient Use; Extra Large. Box of 10	Class IIa, Rule 11 of Annex IX
6	777002XS	Infant Flow LP nasal mask, Single Patient Use; Extra Small. Box of 10	Class IIa, Rule 11 of Annex IX
7	777002S	Infant Flow LP nasal mask, Single Patient Use; Small. Box of 10	Class IIa, Rule 11 of Annex IX
8	777002M	Infant Flow LP nasal mask, Single Patient Use; Medium. Box of 10	Class IIa, Rule 11 of Annex IX
9	777002L	Infant Flow LP nasal mask, Single Patient Use; Large. Box of 10	Class IIa, Rule 11 of Annex IX
10	777002XL	Infant Flow LP nasal mask, Single Patient Use; Extra Large. Box of 10	Class IIa, Rule 11 of Annex IX