

# Declaration of Conformity

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

**Manufacturer's Name:** CareFusion

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

**EU Notified Body:** N/A

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

**Conformity Assessment:** MDD Annex VII

**Quality System:** ISO 13485: 2003

**Type of Equipment:** Breathing Circuits and Masks

**Trade name:** Infant Flow LP

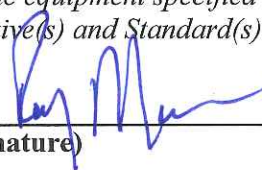
**Model Numbers** See Page 2

**Device Classification:** Class I, Rule 1 of Annex IX

*CareFusion hereby declares that the equipment specified above conforms to the above Directive(s) and Standard(s).*

**Place:** Yorba Linda, CA USA

**Date:** 08-17-2012

  
\_\_\_\_\_  
(Signature)

**Roy Moser**  
\_\_\_\_\_  
(Full Name)

**Manager, Regulatory Affairs**  
\_\_\_\_\_  
(Position/Title)



**CareFusion**

**Infant Flow LP Components**

	<b>Part Number</b>	<b>Description</b>	<b>Classification</b>
<b>1</b>	777040XS	Infant Flow LP Headgear, single Patient use; extra small, 17-21 cm. Box of 10	Class I, Rule I of Annex IX
<b>2</b>	777040S	Infant Flow LP Headgear, single Patient use; small, 21-26 cm. Box of 10	Class I, Rule I of Annex IX
<b>3</b>	777040SM	Infant Flow LP Headgear, single Patient use; small-med, 24-28 cm. Box of 10	Class I, Rule I of Annex IX
<b>4</b>	777040M	Infant Flow LP Headgear, single Patient use; medium, 26-32 cm. Box of 10	Class I, Rule I of Annex IX
<b>5</b>	777040L	Infant Flow LP Headgear, single Patient use; large, 32-37 cm. Box of 10	Class I, Rule I of Annex IX
<b>6</b>	777040XL	Infant Flow LP Headgear, single Patient use; extra large, 37-42 cm. Box of 10	Class I, Rule I of Annex IX
<b>7</b>	777010	Infant Flow LP Bonnet, single Patient use; Size 000, White, 18-20 cm. Box of 10	Class I, Rule I of Annex IX
<b>8</b>	777012	Infant Flow LP Bonnet, single Patient use; Size 00, Grey, 20-22 cm. Box of 10	Class I, Rule I of Annex IX
<b>9</b>	777014	Infant Flow LP Bonnet, single Patient use; Size 0, Pink, 22-24 cm., Box of 10	Class I, Rule I of Annex IX
<b>10</b>	777016	Infant Flow LP Bonnet, single Patient use; Size 1, Lt brown, 24 -26 cm. Box of 10	Class I, Rule I of Annex IX
<b>11</b>	777018	Infant Flow LP Bonnet, single Patient use; Size 2, Yellow, 26-28 cm. Box of 10	Class I, Rule I of Annex IX
<b>12</b>	777020	Infant Flow LP Bonnet, single Patient use; Size 3, Lt blue, 28-30 cm. Box of 10	Class I, Rule I of Annex IX
<b>13</b>	777022	Infant Flow LP Bonnet, single Patient use;, Size 4, Gold, 30-32 cm. Box of 10	Class I, Rule I of Annex IX
<b>14</b>	777024	Infant Flow LP Bonnet, single Patient use; Size 5, Green, 32-34 cm. Box of 10	Class I, Rule I of Annex IX
<b>15</b>	777026	Infant Flow LP Bonnet, single Patient use; Size 6, Lt burgundy, 34-36 cm. Box of 10	Class I, Rule I of Annex IX
<b>16</b>	777028	Infant Flow LP Bonnet, single Patient use; Size 7, Orange, 36-38 cm. Box of 10	Class I, Rule I of Annex IX