

Declaration of Conformity – European Union  
Infant resuscitators and accessories

|  |   |
|--|---|
| <b>Manufacturer:</b>   | Fisher & Paykel Healthcare Ltd<br>15 Maurice Paykel Place, East Tamaki,<br>Auckland 2013, New Zealand   |
| <b>Authorised Representative:</b>  | Fisher & Paykel Healthcare Ltd<br>Unit 16, Cordwallis Park, Clivemont Road,<br>Maidenhead SL6 7BU, United Kingdom   |
| <b>Product Category:</b>   | Gas powered pulmonary resuscitators   |
| <b>Medical Device Family:</b>  | Infant resuscitators and accessories  |
| <b>Conformity Assessment Route:</b>  | Annex II (for class IIa and above)<br>Annex VII (for class I)   |
| <b>Validity of this declaration:</b>   | This Declaration of Conformity, for each model listed, is valid from the start date recorded against the model and for as long as the model is listed on the DoC. When a model is no longer covered by the DoC, it is transferred to a Discontinued Medical Devices list and an end date recorded against it. |
| <p>We, the manufacturer, declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices.<br/>All supporting documentation is retained by the manufacturer.</p> |   |
| <b>Notified Body:</b>  | TÜV SÜD Product Service GmbH<br>Ridlerstr 65, D-80339 München, Germany  |
| <b>Identification number:</b>  | CE 0123   |

Approval

| Name         | Title                      | Signature  | Date and Location         |
|--------------|----------------------------|--|---------------------------|
| Adele Bindon | Regulatory Affairs Manager |  | Auckland, NZ<br>12 MAY 15 |

Declaration of Conformity – European Union  
Infant resuscitators and accessories

Doc. No: REG-56

Revision: M

| REF         | Product Description            | Class | GMDN Code | MDD rule number | Start Date  |
|-------------|--------------------------------|-------|-----------|-----------------|-------------|
| 900IW130D   | NEOPUFF MODULE DAN             | IIb   | 13366     | Rule 9 scl 2    | 14/Dec/1999 |
| 900IW130E   | NEOPUFF INFANT RESUSCITATOR    | IIb   | 13366     | Rule 9 scl 2    | 13/May/1998 |
| 900IW130F   | NEOPUFF MODULE FRE             | IIb   | 13366     | Rule 9 scl 2    | 05/Feb/1999 |
| 900IW130G   | NEOPUFF MODULE GER             | IIb   | 13366     | Rule 9 scl 2    | 12/Aug/1998 |
| 900IW130L   | NEOPUFF MODULE ITA             | IIb   | 13366     | Rule 9 scl 2    | 17/Nov/1998 |
| 900IW130M   | NEOPUFF MODULE FIN             | IIb   | 13366     | Rule 9 scl 2    | 14/Dec/1999 |
| 900IW130N   | NEOPUFF MODULE DUTCH           | IIb   | 13366     | Rule 9 scl 2    | 05/Feb/1999 |
| 900IW130S   | NEOPUFF MODULE SPA             | IIb   | 13366     | Rule 9 scl 2    | 09/Mar/1999 |
| 900IW130T   | NEOPUFF MODULE POR             | IIb   | 13366     | Rule 9 scl 2    | 14/Dec/1999 |
| 900IW130V   | NEOPUFF MODULE NOR             | IIb   | 13366     | Rule 9 scl 2    | 23/Aug/1999 |
| 900IW130W   | NEOPUFF MODULE SWE             | IIb   | 13366     | Rule 9 scl 2    | 21/Dec/1998 |
| 900RD008    | GAS SUPPLY LINE SHORT 10BX     | IIa   | 37498     | Rule 2          | 12/Dec/2002 |
| 900RD009    | GAS SUPPLY LINE LONG 10BX      | IIa   | 37498     | Rule 2          | 12/Dec/2002 |
| 900RD010    | S/USE RESUS KIT W/O MASK 10BX  | IIa   | 37498     | Rule 2          | 12/Dec/2002 |
| 900RD014-10 | S/USE RESUS KIT W/42mm MSK(10) | IIa   | 37498     | Rule 2          | 24/Oct/2006 |
| 900RD015-10 | S/USE RESUS KIT W/50mm MSK(10) | IIa   | 37498     | Rule 2          | 24/Oct/2006 |
| 900RD016-10 | S/USE RESUS KIT W/60mm MSK(10) | IIa   | 37498     | Rule 2          | 24/Oct/2006 |
| 900RD101    | GAS INLET ADAPTOR - 10 PACK    | IIa   | 37498     | Rule 2          | 29/Jun/2000 |
| 900RD110    | S/USE RESUS HUMID W/O MSK 10PK | IIb   | 37498     | Rule 9 scl 2    | 18/Aug/2004 |
| 900RD301    | SIDE MOUNTING BLOCK            | I     | 37075     | Rule 1          | 04/Jun/1999 |
| 900RD302    | WALL MOUNT BRACKET             | I     | 37075     | Rule 1          | 28/May/1999 |
| 900RD303    | NEOPUFF RAIL BRACKET           | I     | 37075     | Rule 1          | 17/Apr/2002 |
| BC513-01    | Neopuff Ohmeda Assembly kit    | I     | 37075     | Rule 1          | 30/Oct/2008 |
| RD020-01    | TEST LUNG NON LATEX            | I     | 12408     | Rule 1          | 30/May/2007 |
| RD050-01    | NEOPUFF CENTRAL MTG BKT        | I     | 37075     | Rule 1          | 13/Apr/2004 |
| RD1300-10   | Kit Resus Adjustable 10        | IIa   | 37498     | Rule 2 scl 1    | 01/Oct/2010 |
| RD1301-10   | KIT RESUS ADJ GASLINE 10       | IIa   | 37498     | Rule 2 scl 1    | 29/Nov/2010 |
| RD1330-10   | KIT RESUS ADJ MSK 35mm         | IIa   | 37498     | Rule 2 scl 1    | 01/Oct/2010 |
| RD1331-10   | KIT RESUS ADJ MSK35 GASLINE 10 | IIa   | 37498     | Rule 2 scl 1    | 29/Nov/2010 |
| RD1340-10   | KIT RESUS ADJ MSK 42mm         | IIa   | 37498     | Rule 2 scl 1    | 01/Oct/2010 |
| RD1341-10   | KIT RESUS ADJ MSK42 GASLINE 10 | IIa   | 37498     | Rule 2 scl 1    | 29/Nov/2010 |
| RD1350-10   | KIT RESUS ADJ MSK 50mm         | IIa   | 37498     | Rule 2 scl 1    | 01/Oct/2010 |
| RD1351-10   | KIT RESUS ADJ MSK50 GASLINE 10 | IIa   | 37498     | Rule 2 scl 1    | 29/Nov/2010 |
| RD1360-10   | KIT RESUS ADJ MSK 60mm         | IIa   | 37498     | Rule 2 scl 1    | 01/Oct/2010 |
| RD1361-10   | KIT RESUS ADJ MSK60 GASLINE 10 | IIa   | 37498     | Rule 2 scl 1    | 29/Nov/2010 |
| RD1370-10   | KIT RESUS ADJ MSK 70mm         | IIa   | 37498     | Rule 2 scl 1    | 01/Oct/2010 |
| RD1371-10   | KIT RESUS ADJ MSK72 GASLINE 10 | IIa   | 37498     | Rule 2 scl 1    | 29/Nov/2010 |
| RD800-EN    | S/USE NEO MASK STARTER KIT     | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD800-SK    | MASK ROUND STRTR KIT S/USE UNI | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD803-10    | S/USE NEO MASK 35MM 10BX       | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD804-10    | S/USE NEO MASK 42MM 10BX       | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD805-10    | S/USE NEO MASK 50MM 10BX       | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD806-10    | S/USE NEO MASK 60MM 10BX       | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD807-10    | S/USE NEO MASK 72MM 10BX       | IIa   | 57824     | Rule 2 scl 1    | 26/May/2006 |
| RD900ADU    | NEOPUFF INFANT RESUSCITATOR DA | IIb   | 13366     | Rule 9 scl 2    | 14/Dec/1999 |

**Declaration of Conformity – European Union  
 Infant resuscitators and accessories**

Doc. No: REG-56

Revision: M

| REF      | Product Description            | Class | GMDN Code | MDD rule number | Start Date  |
|----------|--------------------------------|-------|-----------|-----------------|-------------|
| RD900AEU | NEOPUFF INFANT RESUSCITATOR    | IIb   | 13366     | Rule 9 scl 2    | 21/Aug/1998 |
| RD900AFU | NEOPUFF INFANT RESUSCITATOR FR | IIb   | 13366     | Rule 9 scl 2    | 05/Feb/1999 |
| RD900AGU | NEOPUFF INFANT RESUSCITATOR GE | IIb   | 13366     | Rule 9 scl 2    | 12/Aug/1998 |
| RD900ALU | NEOPUFF INFANT RESUSCITATOR IT | IIb   | 13366     | Rule 9 scl 2    | 17/Nov/1998 |
| RD900AMU | NEOPUFF INFANT RESUSCITATOR FI | IIb   | 13366     | Rule 9 scl 2    | 14/Dec/1999 |
| RD900ANU | NEOPUFF INFANT RESUSCITATOR NL | IIb   | 13366     | Rule 9 scl 2    | 05/Feb/1999 |
| RD900ASU | NEOPUFF INFANT RESUSCITATOR SP | IIb   | 13366     | Rule 9 scl 2    | 09/Mar/1998 |
| RD900ATU | NEOPUFF INFANT RESUSCITATOR PO | IIb   | 13366     | Rule 9 scl 2    | 14/Dec/1999 |
| RD900AVU | NEOPUFF INFANT RESUSCITATOR NO | IIb   | 13366     | Rule 9 scl 2    | 23/Aug/1998 |
| RD900AWU | NEOPUFF INFANT RESUSCITATOR SW | IIb   | 13366     | Rule 9 scl 2    | 12/Dec/1998 |

| GMDN Code | Term   |
|-----------|--|
| 12408     | Lung simulator                                       |
| 13366     | Automatic pneumatic pulmonary resuscitator, reusable |
| 37075     | General-purpose device mount                         |
| 37498     | Oxygen therapy system                                |
| 57824     | Resuscitator face mask, single-use                   |