



# DECLARATION OF CONFORMITY



Respironics Respiratory  
Drug Delivery (UK) Ltd  
Chichester Business Park  
City Fields Way, Tangmere  
Chichester, PO20 2FT, UK.

**Declares under our sole responsibility that the product:**

Product Name: **OPTICHAMBER DIAMOND VALVED HOLDING CHAMBER**

Product Part Number: See list below

Start of CE marking: July 2013

Device Classification: Class I Rule: 5

Global Medical Device Nomenclature Code (GMDN): 38018

Product Options/Accessories: See list below

Valid until: 05-APR-2022

**To which this Declaration relates is in conformity with the provisions of:**

- **Council Directive: 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC.**
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The device/s listed above have been verified as conforming via the procedure relating to the EC Declaration as set out in Annex VII of the Council Directive

Notified Body: N/A – Class I device

Identification Number: Class I device

Authorized EU Representative: N/A – Manufacture is UK based.

Supplementary Information:

The products listed above have been tested in a typical configuration as described in the manufacturer’s accompanying documentation, and are fully compliant with the harmonized standards listed below. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation:

<b>Harmonized Standard:</b>	<b>Title:</b>
EN ISO 13485:2012/AC:2012	Medical devices – Quality management systems. Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices. Part 1: Evaluation & testing within a risk management process.
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2017	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

**Signature:**

**Date:**

**Printed Name:**

**Title:** QA/RA Manager

**Place of Issue:** Chichester, PO20 2FT, UK



## DECLARATION OF CONFORMITY

**PHILIPS**

**RESPIRONICS**

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The following is a list of the product options and accessories, including part numbers:

DESCRIPTION	PART NUMBER
OPTICHAMBER DIAMOND - 10 PACK	1077478
OC DIAMOND W/ LARGE MASK 10 PK- US	1079827
OC DIAMOND 50 PACK	1079830
OC DIAMOND W/ SMALL MASK 10 PK- US	1079823
OC DIAMOND W/ MEDIUM MASK 10 PK- US	1079826
LITETOUCH SMALL MASK	1082714
LITETOUCH LARGE MASK	1082716
LITETOUCH MEDIUM MASK	1082715
OPTICHAMBER DIAMOND - ROW	1079820
OPTICHAMBER DIAMOND W/ SMALL MASK- ROW	1079822
OPTICHAMBER DIAMOND W/ MED MSK- ROW	1079825
OPTICHAMBER DIAMOND W/ LRG MSK- ROW	1079828
LITETOUCH LARGE MASK- ROW	1083783
LITETOUCH SMALL MASK-ROW	1083785
LITETOUCH MEDIUM MASK-ROW	1083784
OPTICHAMBER DIAMOND - 10-PACK CANADA	1098213
OPTICHAMBER DIAMOND W/ SM MASK- CANADA	1098214
OPTICHAMBER DIAMOND W/ MED MASK CANADA	1098215
OPTICHAMBER DIAMOND W/ LG MASK CANADA	1098216
DIAMOND-PREFERRED PLUS	1103005
DIAMOND WITH SM MASK-PREFERRED PLUS	1103006
DIAMOND WITH MED MASK-PREFERRED PLUS	1103038
DIAMOND WITH LG MASK-PREFERRED PLUS	1103007
OPTICHAMBER DIAMOND RUSSIA	1109059
OPTICHAMBER DIAMOND W/SML MASK (RUSSIA)	1109060
OPTICHAMBER DIAMOND W/MED MASK (RUSSIA)	1109094
OPTICHAMBER DIAMOND CHINA	1126620
OPTICHAMBER DIAMOND W/LRG MASK CHINA	1126536
OPTICHAMBER DIAMOND W/MED MASK CHINA	1126537
OPTICHAMBER DIAMOND W/SMALL MASK CHINA	1126699
OPTICHAMBER DIAMOND - SINGLE UNIT CARTON	1077478-001
OPTICHAMBER DIAMOND W/LRG MASK SINGLE UNIT	1079827-001
OPTICHAMBER DIAMOND SINGLE UNIT POLYBAG	1079830-001
OPTICHAMBER DIAMOND W/SM MASK SINGLE UNIT	1079823-001
OPTICHAMBER DIAMOND W/MED MASK SINGLE UNIT	1079826-001