EU DECLARATION OF CONFORMITY

RESPIRONICS®

Doc Number REG 2101263
Revision v10

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device(s)/accessories covered by this Declaration are in conformity with all regulations or directives below.

1. Object of the declaration:

Product Name:	Amara Amara SE Amara Gel Amara Gel SE
Product Type:	Full Face Mask
Intended Purpose:	The Amara and Amara Gel Full Face Masks are intended to provide an interface for application of CPAP or bi-level therapy to patients. The masks are for single patient use in the home or multi-patient use in the hospital/institutional environment. The masks are to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed. The Amara SE and Amara Gel SE Full Face Masks are intended to provide a patient interface for application of noninvasive ventilation. The masks are to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The masks are for multi-patient use in the hospital/institutional environment only. The masks are to be used on patients (>66 lbs/30 kg) who are appropriate candidates for noninvasive ventilation.
Product Part Number(s) and Descriptions:	Part Number(s) listed in this section comply with all directives indicated in DoC unless otherwise noted. The following part numbers are compliant with 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC:

Part Number	Device Name/Description
1090220	P Amara Mask w/RS Frame and RS Hgr Int
1090221	S Amara Mask w/RS Frame and RS Hgr Int
1090225	M Amara Mask w/RS Frame and Hgr Int
1090230	P Amara Mask SE w/RS Frame and RS Hgr Int
1090231	S Amara Mask SE w/RS Frame and RS Hgr Int

	1090235 M Amara Mask SE w/RS Frame and Hgr Int 1090228 L Amara Mask w/RS Frame and Hgr Int 1090236 L Amara Mask SE w/RS Frame and Hgr Int 1090420 P Amara Gel Mask w/RS Frame and RS Hgr Int 1090421 S Amara Gel Mask w/RS Frame and RS Hgr Int 1090425 M Amara Gel Mask w/RS Frame and Hgr Int 1090426 L Amara Gel Mask w/RS Frame and Hgr Int 1090430 P Amara Gel Mask SE w/RS Frame and RS Hgr Int 1090431 S Amara Gel Mask SE w/RS Frame and RS Hgr Int 1090435 M Amara Gel Mask SE w/RS Frame and Hgr Int 1090436 L Amara Gel Mask SE w/RS Frame and Hgr Int
Product Options/Accessories Part Number(s) and Descriptions:	N/A
Basic UDI-DI:	N/A
Control Indicator:	Initial Issue Date: / REF (Part Number): 19-Jun-12 / 1090220, 1090221 3-Aug-12 / 1090230 1090231 14-Mar-13 / 1090225, 1090235 19-Jun-13 / 1090228, 1090236 1-Jul-13 / 1090420, 1090421, 1090425, 1090426, 1090430, 1090431, 1090435, 1090436
Global Medical Device Nomenclature code (GMDN) and Description	57814 CPAP/BiPAP Face Mask Reusable

The object of the Declaration (product part numbers and if applicable the component part numbers) that are described above as included in this DoC is / are in conformity with the following regulations / directives. If optional accessories that are used in combination with the product (medical device), but are CE marked on their own are referenced in this DoC, they are excluded further on as these optional accessories have their own DoC.

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)**
Risk Classification	Class IIa based on Annex IX and Rule 2
Conformity Assessment Route	Annex II excluding (4)
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany 0123
Certificate(s) Issued	TÜV SÜD EC Certificate Number: G1 015581 0611
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A.

2. Mandatory information:

Manufacturer	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 USA
EU Authorized Representative (AR):	Respironics Deutschland GmbH & Co. KG Gewerbestrasse 17 82211 Herrsching, Germany Tel: +49 8152 93060
ISO Quality Certificates Issued:	The Manufacturer is certified by TÜV SÜD to the following: TÜV SÜD EN ISO 13485:2016 Certificate Number: Q5 015581 0609 TÜV SÜD MDSAP Certificate Number: QS6 112601 0001

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Signature (signed for and on behalf of):
Respironics, Inc.

Date of Issue: 08 September 2021

Printed Name: Jennifer Richardson

Place of Issue: Murrysville, PA, USA

Title: Senior Manager, Regulatory Affairs

3. Attachment A Standards and/or Common Specifications

Standard	Standard Title
Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Particular Safety Standards	
Patient Interface	
EN ISO 17510-2:2009	Sleep apnoea breathing therapy – Part 2: Masks and application accessories
Biocompatibility	
EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2009	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2009	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
Other Standards	
Accompany Documents and Labeling	
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
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
Risk Management	
ISO 14971:2019	Medical devices – Application of risk management to medical devices
Usability	
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
Cleaning and Disinfection	
EN ISO 17664:2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices