



## EC DECLARATION OF CONFORMITY

<b>Manufacturer</b>	BeaconMedaes Limited. Greaves Close, Markham Vale, Chesterfield, S44 5FB, UK	
<b>EU Authorized Representative</b>	Atlas Copco Airpower n.v. Boomsesteenweg 957, 2610 Wilrijk, Belgium	
<b>Device</b>	Medical Air System	
<b>Brand</b>	BeaconMedaes	
<b>Model Range</b>	Refer to Document 4233550337	
<b>Classification</b>	IIb	
<b>Classification Rule</b>	Non-invasive medical device according to rule 11 of annex IX of the Medical Device Directive 93/42/EEC	
<b>Conformity Route</b>	Annex II (excluding section 4) of MDD No.93/42/EEC as amended	
<b>GMDN Code</b>	36271	
<b>GMDN Term</b>	Medical Gas and Vacuum Supply Systems	
<b>Standards Applied</b>	EN 1041 ISO 3744 ISO 7183 EN ISO 7396-1 ISO 8573-1 ISO 8573-5 ISO 12500-2 EN ISO 14971	EN ISO 15223-1 IEC 61010-1 EN 61326-1 EN 62304 EN 62366 HTM 2022 HTM 02-01
<b>Notified Body</b>	DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	
<b>MDD Certificate(s)</b>	10000368723-PA-NA-SVK	

This EC declaration of conformity is issued under the sole responsibility of the manufacturer. We hereby declare that the above-mentioned products meet the provisions of the Medical Devices Directive 93/42/EEC concerning Medical Devices, as amended. All supporting documentation is retained under the premises of the manufacturer.

**Date:** 06-Dec-2021

**Place of Issue:** Markham Vale

**Signed on behalf of BeaconMedaes Limited:**

**Sean Fairest  
General Manager**