

EC DECLARATION OF CONFORMITY

Manufacturer	BeaconMedaes Limited. Greaves Close, Markham Vale, Chesterfield, S44 5FB, UK	
EU Authorized Representative	Atlas Copco Airpower n.v. Boomsesteenweg 957, 2610 Wilrijk, Belgium	
Device	Medical Gas Terminal Unit	
Brand	BeaconMedaes	
Model Range	Refer to Document 4233550333	
Classification	lla	
Classification Rule	Non-invasive medical device according to rule 2 of annex IX of the Medical Device Directive 93/42/EEC	
Conformity Route	Annex II (excluding section 4) of MDD No.93/42/EEC as amended	
GMDN Code	37544, 45490, 41718, 42510, 47851, 37512, 37694	
GMDN Term	Terminal Unit	
Standards Applied	EN 1041 BS 5682 EN ISO 7396-1 EN ISO 9170-1 EN ISO 14971	EN ISO 15001 EN 15223-1 EN 18082 HTM 02-01
Notified Body	DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	
MDD Certificate(s)	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