

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	Automatic Changeover Manifold	
Brand	BeaconMedaes	
Model Range	Refer to Document 4233550336	
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	36271, 47564	
GMDN Term	Medical Gas and Vacuum Pipeline Systems	
Standards Applied	EN 1041 EN ISO 7396-1 EN ISO 14971 EN ISO 15001 EN ISO 10524-2 EN 15223-1	EN 50581 EN 60601-1 EN 60601-1-2 EN 60601-1-6 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