

EC DECLARATION OF CONFORMITY

Greaves Close, Marknam Vale, Chesterfield, S44 SFB, UK Atlas Copco Airpower n.v. Boomsesteenweg 957, 2610 Wilrijk, Belgium Area Valve Service Unit (AVSU) Brand BeaconMedaes Refer to Document 4233550341 Classification IIa Non-invasive medical device according to rule 2 of annex IX of the Medical Device Directive 93/42/EEC Annex II (excluding section 4) of MDD No.93/42/EEC as amended GMDN Code 44807 Medical Gas Pipeline Systems EN 1041 EN ISO 7396-1 EN ISO 15223-1 EN ISO 18082 HTM 02-01 EN ISO 15001 Notified Body Notified Body Notified Body Number 2460)			
Boomsesteenweg 957, 2610 Wilrijk, Belgium Area Valve Service Unit (AVSU) Brand BeaconMedaes Model Range Refer to Document 4233550341 Ila 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 44807 Medical Gas Pipeline Systems EN 1041 EN ISO 7396-1 EN ISO 15223-1 EN ISO 18082 HTM 02-01 EN ISO 15001 Notified Body Notified Body Refer to Document 4233550341 EN ISO 1930541 EN ISO 15001 DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	Manufacturer		
Brand BeaconMedaes Refer to Document 4233550341 Classification Ila 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 44807 Medical Gas Pipeline Systems EN 1041 EN ISO 15223-1 EN ISO 15223-1 EN ISO 18082 HTM 02-01 EN ISO 15001 Notified Body Notified Body Refer to Document 4233550341 EN ISO 3/42/EEC Annex II (excluding section 4) of MDD No.93/42/EEC as amended EN ISO 100 No.93/42/EEC as amended Annex II (excluding section 4) of MDD No.93/42/EEC as amended EN ISO 1500 No.93/42/EEC as amended Annex II (excluding section 4) of MDD No.93/42/EEC as amended EN ISO 1500 No.93/42/EEC as amended BONDN Term Medical Gas Pipeline Systems EN ISO 15223-1 EN ISO 15023-1 EN ISO 15001 EN ISO 15001 DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	EU Authorized Representative		
Refer to Document 4233550341 Classification IIa 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 44807 Medical Gas Pipeline Systems EN 1041 EN ISO 7396-1 EN ISO 15223-1 EN ISO 18082 HTM 02-01 Notified Body Notified Body Refer to Document 4233550341 IIa Non-invasive medical device according to rule 2 of annex IX of the Medical Gas Pipeline Systems EN IND No.93/42/EEC as amended Annex II (excluding section 4) of MDD No.93/42/EEC as amended EN ISO 1500 1 EN ISO 15223-1 EN ISO 18082 HTM 02-01 DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	Device	Area Valve Service Unit (AVSU)	
Classification Classification Rule Classification Rule Non-invasive medical device according to rule 2 of annex IX of the Medical Device Directive 93/42/EEC Annex II (excluding section 4) of MDD No.93/42/EEC as amended GMDN Code 44807 Medical Gas Pipeline Systems EN 1041 EN ISO 15223-1 EN ISO 7396-1 EN ISO 18082 HTM 02-01 EN ISO 15001 Notified Body Notway (Notified Body Number 2460)	Brand	BeaconMedaes	
Classification Rule Non-invasive medical device according to rule 2 of annex IX of the Medical Device Directive 93/42/EEC Annex II (excluding section 4) of MDD No.93/42/EEC as amended GMDN Code 44807 Medical Gas Pipeline Systems EN 1041 EN ISO 15223-1 EN ISO 7396-1 EN ISO 18082 HTM 02-01 EN ISO 15001 Notified Body DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	Model Range	Refer to Document 4233550341	
conformity Route Conformity Route GMDN Code GMDN Term Medical Gas Pipeline Systems EN 1041 EN ISO 7396-1 EN ISO 14971 EN ISO 15001 Notified Body DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	Classification	Ila	
GMDN Code 44807 GMDN Term Medical Gas Pipeline Systems EN 1041 EN ISO 15223-1 EN ISO 7396-1 EN ISO 18082 EN ISO 14971 HTM 02-01 EN ISO 15001 DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	Classification Rule	Non-invasive medical device according to rule 2 of annex IX of the Medical Device Directive 93/42/EEC	
Medical Gas Pipeline Systems EN 1041 EN ISO 7396-1 EN ISO 15223-1 EN ISO 18082 HTM 02-01 Notified Body Medical Gas Pipeline Systems EN ISO 15223-1 EN ISO 18082 HTM 02-01 DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	Conformity Route		
EN 1041	GMDN Code	44807	
Standards Applied EN ISO 7396-1 EN ISO 14971 EN ISO 15001 EN ISO 18082 HTM 02-01 EN ISO 15001 DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway (Notified Body Number 2460)	GMDN Term	Medical Gas Pipeline Systems	
Norway (Notified Body Number 2460)	Standards Applied	EN ISO 7396-1 EN ISO 14971	EN ISO 18082
MDD Certificate(s) 10000368723-PA-NA-SVK	Notified Body		
	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