Declaration of Conformity

Manufacturer: Atlas Copco Ltd. (trading as Atlas Copco Medical)
Unit 18, Nuffield Way, Abingdon, OX14 1RL, UK

Product: Medical Vacuum Plant

Model Range: PMGS PureMED Vacuum Plant

Classification: IIb

Conformity Route: Annex II


Quality Management Representative: Ken Tombs – QSHE Manager

GMDN Code: 36271

GMDN Term: Medical Gas and Vacuum Supply Systems

Standards Applied: EN 286-1, EN 837-1, EN 1012-1&2, EN 1041, EN ISO 2151, EN 5169, EN ISO 7396-1, EN ISO 10993-1, EN 12100-1&2, EN 13348, EN ISO 13857, EN ISO 14971, EN ISO 15223-1, EN 60204-1, EN 62304, EN 61000-6-1, EN 61000-6-2, EN 61000-6-3, EN 61000-6-4, HTM 2022, HTM 02-01

Notified Body: Lloyd’s Register Quality Assurance Limited, 71 Fenchurch Street, London EC3M 4BS United Kingdom (LRQA Notified Body Number 0088)

MDD Certificate(s): LRQ 4007749/C

Start of CE Marking: 03 APR 2013

Place and Date of Issue: Abingdon, 17 May 2018

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Devices, as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Endorsing Signature
Sanjay Safaya (General Manager)