

EC DECLARATION OF CONFORMITY

with regard to the Medical Device Directive 93/42/EEC

Manufacturer
BeaconMedaes LLC
1059 Paragon Way
Rock Hill, SC 29730 - USA

EC Representative
AtlasCopco Medical
Unit 18 Nuffield Centrum
Abingdon, Oxfordshire
OX14 1RL UK

This declaration is issued under the sole responsibility of the manufacturer.

Object of declaration:

Product: TotalAlert infinity Medical Gas Notification System

Model: A3-MXX, A3-AXX, A3-CXX

("XX" represents a number scheme for different module configurations for each alarm type.)

We hereby declare that an examination has been carried out following the requirements of Annex VII of the EC directive 93/42/EEC as amended by all subsequent directives including 2007/47/EC for the aforementioned medical device as a Class I device.

Directive on the approximation of laws of the Member		Harmonized and/or
States relating to		Technical Standards used
Medical Devices	MDD 93/42/EEC with 2007/47/EC (Amendment)	EN ISO 13485:2012
		EN ISO 14971:2012
		EN 15223-1:2012
		EN ISO 7396-1:2016
		HTM 02-01:Part A 2006
		IEC 60601-1-2:2007

Signed on behalf of: Construction Equipment North America LLC

Place of issue:

1059 Paragon Way, Rock Hill, SC

Date of issue:

Name:

Tim Conner

Position:

Engineering Manager, Medical Gas Products

Signature:

The technical documentation for the device is available from the above address.