

Certificate Number  
615 CE

Initial Certification Date  
07 January 2008

Certificate Issue Date  
18 December 2008

Certificate Expiry Date  
08 January 2014

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than its Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or logo of its clients for the use or advertisement of the listed material, product or service must first be approved in writing by AMTAC.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

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# EC Certificate

**PRODUCTION QUALITY ASSURANCE**  
**Directive 93/42/EEC for Medical Devices, Annex V**

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

## Organization:

### **AIR SAFETY LIMITED**

NFC House, Vickers Industrial Estate, Mellishaw Lane, Morecambe,  
Lancs. LA3 3EN

See attached schedule

Authorized Signatory:

  
Q. NIKVA

AMTAC Certification Services Limited, Milton Keynes, UK

**PRODUCT SCHEDULE FOR CERTIFICATE 615 CE  
AIR SAFETY LIMITED**

- Cat 1. CPAP/BIPAP replacement machine filters  
Non-Sterile
- Cat 2. HME Devices & attachments for Anaesthesia, Respiratory and Critical Care  
Sterile & Non-sterile
- Cat 3. HMEF filters & attachments for Anaesthesia, Respiratory and Critical Care  
Sterile & Non-sterile
- Cat 4. Electrostatic filters & attachments for Anaesthesia, Respiratory and Critical Care  
Sterile & Non-sterile
- Cat 5. Pleated Mechanical filters & attachments for Anaesthesia, Respiratory and Critical Care  
Sterile & Non-sterile
- Cat 6. Laparoscopic Filters, Kits and Associated Accessories  
Sterile & Non-sterile
- Cat 7. Anaesthetic Kits and Associated Accessories  
Sterile & Non-sterile
- Cat 8. Vent Filters  
Sterile & Non-sterile
- Cat 9. Suction Filters  
Sterile & Non-sterile
- Cat 10. Surgical Smoke Plume Filters and Scavenging Devices  
Non-Sterile
- Cat 11. Replacement Machine Filters  
Non-Sterile

Original Issue Date: 07 January 2004

Authorized Signatory:

Certificate Issue Date: 19 December 2008

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