Sistemi s.r.l.

Pianezza, 15th September 2008

Medical Devices Directive

Manufacturer name: AMBRA SISTEMI s.r.l.
Address: Via Collegno 45 bis
I-10044 PIANEZZA TO

93/42/CE

declares following devices

DECLARATION

Device name: SDAMGUARD-MED
Accesories: All

of

CONFORMITY

satisfy the essential basic safety requirements of the European Directive 93/42/CE concerning medical devices. With reference to Annex IX – Rule IX of same directive, the above mentioned devices are Medical Devices in class IIb within the limits of following intended purpose:

I) Alarm repeater for SDAM-Med medical devices, assigned to medical gases storage and supply systems and working in accordance with their specific intended purpose.

CE

Additional notes:

⇒ Devices can be connected to IT power systems
⇒ Certificate MED 28016 contains the results of the EC design-examination, performed by the notified body number 0476.

0476

Claudio Guidotti
technical manager

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