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*

**Device name:** SDAM-MED
**Variants:** D10, A5, R

DECLARATION 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 monitoring in 2nd stage pressure regulator units, belonging to medical gases storage and supply systems, in combination with pressure switches or 4…20 mA pressure transducers, in accordance with EN ISO 7396-1.
II) Alarm monitoring in medical gas storage systems and corresponding supply pipelines, in combination in combination with pressure switches or 4…20 mA pressure transducers, in accordance with EN ISO 7396-1.

**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.

CE 0476

*Claudio Guidotti*
technical manager

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