Sistemi s.r.l.

Medical Devices Directive

Manufacturer name: AMBRA SISTEMI s.r.l.

Address: Via Collegno 45 bis
I-10044 PIANEZZA TO

93/42/CE

declares that following devices

Device name: FLOTEL-MED

DECLARATION of CONFORMITY

comply with all the requirements of the European Directive 93/42/CE, modified by the 2007/47/CE, concerning medical devices, particularly with the basic safety requirements of the Annex I, according to the EC Quality assurance System Certificate MED 28016 released by the notified body number 0476 with reference to the Annex II of the same directive.

Annexes:

⇒ EC Quality assurance System Certificate MED 28016 by the notified body number 0476

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technical manager
Claudio Guidotti

CE 0476

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