



CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

C.F. di Ciro Fiocchetti & C. s.n.c. *fiocchetti*
THE COLD MANUFACTURER

Via Lorenzini, 53

I - 42045 Luzzara (RE)

has established and applies a quality management system
for the following scope:

**Design, development, manufacturing, distribution and after-sales service
of medical devices (blood bank, plasma freezer and accessories) EA 19**

Through an Audit, Report No. 0470905, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI EN ISO 13485:2004

evaluated according to the requirements of the Document SINCERT RT-20.

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0470905**.

This Certificate is valid from 2009-11-06 to 2012-11-05.

The reference date for all the next audits is (day-month): 24-06.

Milan, 2009-11-06.

The certification responsible
TÜV Rheinland Italia S.r.l., Via E. Mattei, 10 - I - 20010 Pogliano Milanese (MI) *

This certificate does not represent proof that the statutory requirements of
the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.



SGQ N° 083A

Membro degli Accordi di Mutuo Riconoscimento EA ed IAF
Signatory of EA and IAF Mutual Recognition Agreements

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