



CERTIFICATE

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

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

Bio Development S.r.l.

S.S. Sempione, 32

I - 20015 Parabiago (MI)



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

Design, manufacture management and own brand marketing of in-vitro diagnostic medical devices for Internal Quality Control (IQC). External Quality Management Scheme (EQAS) and intra-interlaboratory quality control (IQC) for Clinical Laboratories. EA 29a, 19

Through an Audit, Report No. 1180610, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI EN ISO 9001:2008

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

Certificate Registration No. **39 00 1180610**.

This Certificate is valid from 2010-10-04 to 2013-08-08.

The reference date for all the next audits is (day-month): 20-07.

Milan, 2010-10-04. First Certification: 2007-08-09

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



SGQ N° 083A
Membro degli Accordi di Mutuo Riconoscimento EA ed IAF
Signatory of EA and IAF Mutual Recognition Agreements

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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.

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This Certificate is valid from 2010-10-04 to 2013-08-08.

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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.



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