Roma, 30th September 2014

To whom it may concern

Dear Mrs Fiorenza Messina,

for regulatory purposes is not mandatory to add into the EC Certificate all the brands of an in vitro diagnostic medical device marketed under client's brand. GIMA company chooses for commercial reasons to add them. Many companies do not put them in fact, including those from which GIMA buys products with its brand, but for which GIMA is not manufacturer.

Since it is not mandatory to include the customer brands in the certificate, you can market a product identical to those already approved, even if not added as a brand in the EC certificate, provided that the Notified Body should be notified about the new label before placing on the market.

If you have any doubts, we are at your disposal.

Kind regards,

QuaSer s.r.l.
Ing. Bruno Bisione

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