



Product Service

EC Design Examination Certificate

(Annex IV, section 4 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No. V7 06 03 49408 009

Manufacturer: **BAG - Biologische Analysensystem GmbH**
 Amtsgerichtsstr. 1-5
 35423 Lich
 GERMANY

Product: **Reagents and Reagents products for blood typing**
Monoclonal Anti-Sera: Anti-A, Anti-B, Anti-A, B

Model(s): **Anti-A (AB0 1)**
Anti-B (AB0 2)
Anti-A, B (AB0 1, 2)

Parameters:

Name:	Clone:	Id-No.:
-	-	-
Anti-A	F987C6	6790, 6791, 6792
Anti-B	F843D6, F972D6	6793, 6794, 6795
Anti-A, B	F987C6, F843D6, F972D6, F1257B6	6796, 6797, 6798

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the aforementioned devices according to Annex IV, section 4 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The design of the devices conforms to the provisions of this Directive. See also notes overleaf.

Report No.: 70120441

Valid until: 2009-03-31



Date, 2006-04-03

Reiner Krumme

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices with identification no. 0123.

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