



EC Design Examination Certificate

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

No. V7 03 12 49408 004

Manufacturer: **BAG – Biologische
Analysensystem GmbH**
Amtsgerichtsstrasse 1-5
D - 35423 Lich

Product: **Reagents for Blood Grouping for
the Rh-System**

The Certification Body of TÜV 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.: 70060888

Valid until: 2008-12-18

Date: 2003-12-19

A handwritten signature in black ink, appearing to be 'R. Kne', written over a light blue grid background.



TÜV 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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No. V7 03 12 49408 004

Model(s): Anti-C monoclonal (IgM)
 Anti-c monoclonal (IgM)
 Anti-E monoclonal (IgM)
 Anti-e monoclonal (IgM)
 Anti-K (Kell) monoclonal (IgM)
 Rh-Kontrolle

Parameters:	Clone:	Id-No.:
	Anti-C Klon: MS24	6751, 6752
	Anti-C Klon: F388F3	6753, 6754
	Anti-c Klon: MS33	6757, 6758
	Anti-c Klon: C116C15A	6744, 6745
	Anti-E Klon: MS258	6755, 6756
	Anti-E Klon: E1.16C.10F	6746, 6747
	Anti-e Klon: MS62/69	6728, 6729
	Anti-e Klon: MS16/21/63	6759, 6760
	Anti-K (Kell)Klon: MS56	6777, 6778
	Anti-K Klon: K1.1.21HM.EF	6774, 6775
	Rh-Kontrolle	6748, 6749