

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith grants



Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany

for the scope

blood grouping reagents:

HumaType Anti-A (monoclonal, mouse, IgM, clone 11H5),
HumaType Anti-B (monoclonal, mouse, IgM, clone 6F9),
HumaType Anti-AB (monoclonal, mouse, IgM, clones 5E10/2D7),
HumaType Anti-D (monoclonal, human, IgM, clone RUM-1),
HumaType Anti-D (monoclonal, human, IgM/IgG, clones TH-28/MS-26),
HumaType ABO/D Kit

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven
that the design meets the requirements according to

Annex IV – Section 4 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate
according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from	2011-03-14
Valid until	2016-03-14
Registration no.	0063.32.06/0
Report no.	E 0063.32 / 2011-03-14
Stuttgart	2011-03-14

Head of Certification Body

