

Declaration of Conformity

Manufacturer:

Immucor Gamma
Immucor Medizinische Diagnostik GmbH
Adam-Opel-Strasse 26
Post Office Box 20 02 65
D-63322 Roedermark
Germany
phone 49-6074-8420-0
fax 49-6074-8420-99

Product: **see appendix**

Classification: Self-Declare under Directive 98/79/EC

Conformity assessment route: Annex III of Directive 98/79/EC

We hereby declare that the above mentioned products meet the provisions of the council directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:

- **DIN EN ISO 13485:2007** Medical Devices – Quality Management Systems - Requirements for regulatory purposes.
- **DIN EN ISO 14971:2007** Medical Devices-Application of risk management to medical devices.
- **DIN EN 13612:2002** Performance evaluation of in vitro diagnostic medical devices
- **DIN EN 13640:2002** Stability testing of in vitro diagnostic reagent
- **DIN EN 375:2001** Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- **ISO 15223-1:2007** Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
- **DIN EN 980:2008** Symbols for use in the labelling of medicals devices

Notified body: Lloyds Register Quality Assurance (LRQA)

Supersedes version of 2008-03-17

Place, date of issue: Rödermark, 2009-01-30

Signature:



Name: Dr. Bernhard Ciommer

Position: Director RA/QA & Technical
Services International

Appendix to “Declaration of Conformity”

Description	Product Number(s)
immuClone Anti-M	0009506
immuClone Anti-M Galileo	0066021
immuClone Anti-N IgM	0009605
immuClone Anti-S IgM	0009905
immuClone Anti-s IgM	0009909
immuClone Anti-H IgM	0009525
immuClone Anti-H Galileo IgM	0066005
immuClone Anti-Le(a) IgM	0004162
immuClone Anti-Le(b) IgM	0004164
immuClone Anti-C ^w IgM	0007603
immuClone Anti-C ^w Galileo IgM	0066019
immuClone Anti-C3d	0003322
immuClone Anti-P(1) IgM	0008150