

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: List B, Annex II of Directive 98/79/EC

Conformity assessment route: Annex IV 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:

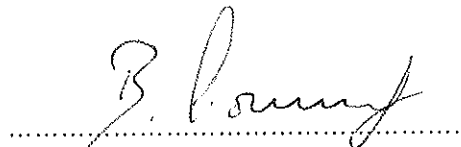
- **DIN EN ISO 13485:2007** Medical Devices – Quality Management Systems - Requirements for regulatory purposes.
- **DIN EN ISO 14971:2007** Medical Devices-Application of risk management to medical devices.
- **DIN EN 13612:2002** Performance evaluation of in vitro diagnostic medical devices
- **DIN 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 2008-01-16

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-Jk(a)	0008306
immuClone Anti-Jk(b)	0008315
Anti-Fy(a)	0008205
Anti-Fy(b)	0008210
Anti-Jk(a) micro	0066302
Anti-Jk(b) micro	0066303
Anti-Fy(a) micro	0066300
Anti-Fy(b) micro	0066301
Negative Control micro	0066299
Anti-Human Globulin Serum, (Anti-IgG, -C3d), green	0004810; 0004848; 0004850