

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 A, 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:

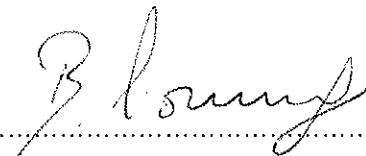
- **DIN EN ISO 13485:2007** Medical Devices – Quality Management Systems - Requirements for regulatory purposes.
- **DIN EN ISO 14971:2007** Medical Devices-Application of risk management to medical devices.
- **DIN EN 13612:2002** Performance evaluation of in vitro diagnostic medical devices
- **DIN 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 2008-03-31

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

Signature:


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Name: Dr. Bernhard Ciommer

Position: Director RA/QA & Technical
Services International

Appendix to “Declaration of Conformity”

Products	Product Number(s)
immuClone Anti-A IgM	0006401; 0006400
immuClone Anti-A Galileo IgM	0066001; 0066080
immuClone Anti-B IgM	0006407; 0006406
immuClone Anti-B Galileo IgM	0066002; 0066081
immuClone Anti-A,B IgM	0006409; 0006408
immuClone Anti-A,B Galileo IgM	0066003; 0066082
immuClone Anti-D rapid IgM	0007117; 0007127
immuClone Anti-D rapid Galileo IgM	0066008; 0066085
immuClone Anti-D fast IgM	0007116; 0007126
immuClone Anti-D fast Galileo IgM	0066007; 0066084
immuClone Anti-D duo IgM + IgG	0006196; 0006199
immuClone Anti-D duo Galileo IgM + IgG	0066009; 0066086
immuClone Anti-CDE IgM + IgG	0006820; 0006821
immuClone Anti-CDE Galileo IgM + IgG	0066010
immuClone (1) Anti-C IgM	0007206; 0007204; 0007216; 0007214
immuClone (1) Anti-C Galileo IgM	0066011
immuClone (1) Anti-c IgM	0007306; 0007304; 0007316; 0007314
immuClone (1) Anti-c Galileo IgM	0066013
immuClone (1) Anti-E IgM	0007406; 0007404; 0007416; 0007414
immuClone (1) Anti-E Galileo IgM	0066015
immuClone (1) Anti-e IgM	0007506; 0007504; 0007516; 0007514
immuClone (1) Anti-e Galileo IgM	0066017
immuClone (2) Anti-C IgM	0007207; 0007205; 0007217; 0007215
immuClone (2) Anti-C Galileo IgM	0066012
immuClone (2) Anti-c IgM	0007307; 0007305; 0007317; 0007315
immuClone (2) Anti-c Galileo IgM	0066014
immuClone (2) Anti-E IgM	0007407; 0007405; 0007417; 0007415
immuClone (2) Anti-E Galileo IgM	0066016
immuClone (2) Anti-e IgM	0007507; 0007505; 0007517; 0007515
immuClone (2) Anti-e Galileo IgM	0066018
immuClone (1) Anti-K (Kell) IgM	0008016; 0008026



TECHNICAL FILE: TF-GER-201 (List A)

Products	Product Number(s)
immuClone (1) Anti-K Galileo (Kell) IgM	0066020
immuClone (2) Anti-K (Kell) IgM	0008014
immuClone (2) Anti-K (Kell) Galileo IgM	0066038
Anti-K (Kell) quick	0008015; 0008050
Automated immuClone Anti-K (Kell) Galileo IgM	0066088
immuClone Rh-Hr Control	0006720; 0006721
immuClone Rh-Hr Control Galileo	0066006; 0066083
NOVACLONE Anti-D IgM + IgG	0086196; 0086199
NOVACLONE Anti-D Galileo IgM + IgG	0066036; 0066037