

UAB „Prosangvis“

V. Putvinskio g. 38-10, LT-44211 Kaunas, tel. +370 652 42269

Duomenys kaupiami ir saugomi Juridinių asmenų register, kodas 300089105, PVM kodas LT100001537918

Viešajai įstaigai Nacionaliniam kraujo centrui

**PASIŪLYMAS
DĖL VIEŠOJO MAŽOS VERTĖS DIAGNOSTINIŲ REAGENTŲ, SKIRTŲ DONORO
KRAUJO IMUNOHEMATOLOGINIŲ TYRIMŲ ATLIKIMUI ANALIZATORIAIS
GALILEO NEO, PIRKIMO**

2020-02-26 Nr. PRS200226.1

(Data)

Kaunas

(Sudarymo vieta)

Tiekėjo pavadinimas / <i>Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių pavadinimai/</i>	UAB „Prosangvis“
Tiekėjo adresas / <i>Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių adresai/</i>	V. Putvinskio g. 38-10, LT44211 Kaunas
Už pasiūlymą atsakingo asmens vardas, pavardė, pareigos	Direktorius Valdas Petkevičius
Telefono numeris	+370 652 42269, +370 656 14698
Fakso numeris	-
El. pašto adresas	info@prosangvis.lt

Šiuo pasiūlymu pažymime, kad sutinkame su visomis pirkimo sąlygomis, reikalavimais, pateiktais šiuose pirkimo dokumentuose, jų paaiškinimuose, papildymuose. Patvirtiname, kad pasiūlyme pateikta informacija yra teisinga ir apima viską, ko reikia tinkamam pirkimo sutarties įvykdymui.

Pastaba. Pildoma, jei Tiekėjas ketina pasitelkti subteikėją(-us), subteikėją(-us):

Subteikėjo(-ų), subteikėjo(-ų) pavadinimas(-ai) (jeigu žinomas)	
Subteikėjo(-ų), subteikėjo(-ų) adresas(-ai)	
Pirkimo sutarties dalies, perduodamos vykdyti subteikėjui, aprašymas	

Mes siūlome šias prekes, kurios atitinka pirkimo dokumentuose nurodytus reikalavimus:

Eil. Nr.	Tyrimų, reagentų ir papildomų priemonių pavadinimai	Maksimalus tyrimų skaičius	Reagentų ir eksploatacinių medžiagų kiekis (ml./vnt.) maksimaliam tyrimų skaičiui	Reagentų ir eksploatacinių medžiagų reikalingų vienam tyrimui atlikti, kaina, Eur be PVM	Suma Eur be PVM (3 x 5)	Gamintojas, komercinės prekės pavadinimas
1	2	3	4	5	6	7
1.	Kraujo grupės pagal ABO (tiesioginės ir atvirkštinės agliutinacijos būdu) ir RhD (tipo) nustatymas	14 000	-	0,95	13300,00	Immucor
1.1	Mikroplokštelės	-	15	-	-	Microplates (0066050)
1.2	Skiediklis	-	4	-	-	Diluent (0066058)
1.3	Anti-A IgM	-	3	-	-	Immucor Anti-A IgM (0066080)
1.4	Anti-B IgM	-	3	-	-	Immucor Anti-B IgM (0066081)
1.5	Anti-A,B IgM	-	3	-	-	Immucor Anti-A,B IgM (0066082)
1.6	Anti-D IgM	-	3	-	-	Immucor Anti-D rapid IgM (0066085)
1.7	Anti-D IgM+IgG	-	3	-	-	Novacclone Anti-D IgM+IgG monoclonal (0066086)
1.8	Rh kontrolė	-	5	-	-	Immucor Rh-Hr Control (0066083)
1.9	Referentinės ląstelės A1 ir B	-	26	-	-	Reference cells -2 A1 and B (0002345)
Bendra pasiūlymo kaina Eur be PVM					13300,00	X
PVM suma, Eur:					2793,00	X
Bendra pasiūlymo kaina Eur su PVM					16093,00	x

Bendra pasiūlymo kaina, įskaitant visas išlaidas ir visus mokesčius, su PVM – 16093,00 Eur (šešiolika tūkstančių devyniasdešimt trys eurai), taikomas PVM dydis – 21 proc., sudaro 2793,00 Eur.

Jei eilutės „PVM tarifas, proc.“, „PVM suma“ nepildomos arba pasiūlymas teikiamas su sumažintu PVM mokesčiu, nurodomos priežastys, dėl kurių PVM nemokamas arba PVM sumažintas:

Pasiūlyme pateikiami šie dokumentai:

Eil. Nr.	Pateiktų dokumentų pavadinimas	Dokumento puslapių skaičius
1.	0002345	2
2.	0066037	3
3.	0066058	2
4.	0066080 0066081 0066082	4
5.	0066083	3
6.	Anti_A_B_AB_RS	3
7.	Anti_D_anti_Kell_RS	4
8.	EC Certificate Full Quality Assurance Immucor GmbH	3
9.	EC Design Certificate - 03.TF.0001 List A - Immucor GmbH 2023-12-07	3
10.	ISO 9001-2015 Immucor Med. Diagnostik GmbH	3
11.	Reference_cells_0002345_RS	4
12.	Rh_control_0066006_RS	3
13.	Patvirtinimas dėl kokybės sertifikatų	1
14.	CE Galileo Diluent (2 psl.)	3
15.	CE RED BLOOD CELLS (2 psl.)	3
16.	GALILEO NEO naudotojo vadovas (364 psl.)	455

Ši pasiūlyme nurodyta informacija yra konfidenciali /Perkančioji organizacija šios informacijos negali atskleisti tretiesiems asmenims/:

Eil. Nr.	Pateikto dokumento pavadinimas

Pastaba. Tiekėjui nenurodžius, kokia informacija yra konfidenciali, laikoma, kad konfidencialios informacijos pasiūlyme nėra.

Direktorius
(Tiekėjo vadovo arba jo įgalioto asmens pareigų pavadinimas)

El. parašas
(parašas)

Valdas Petkevičius
(vardas, pavardė)

Dokumentą elektroniniu parašu pasirašė VALDAS PETKEVIČIUS
Data: 2020-02-26 17:24:39

UAB „Prosangvis“

V. Putvinskio g. 38-10, LT-44211 Kaunas, tel. +370 652 42269
Duomenys kaupiami ir saugomi Juridinių asmenų registre, kodas 300089105, PVM kodas LT100001537918

VšĮ Nacionaliniam kraujo centrui

PATVIRTINIMAS DĖL KOKYBĖS SERTIFIKATŲ

2020 m . vasario 26 d. Nr. PRS200226.2

Kaunas

Mes, UAB „Prosangvis“, dalyvaudami VšĮ Nacionalinio kraujo centro vykdomoje skelbiamoje apklausoje „Diagnostiniai reagentai, skirti donorų kraujo imunohematologinių tyrimų atlikimui analizatoriais Galileo NEO“, pirkimo Nr. 474261, šiuo raštu patvirtiname, kad mūsų siūlomų gamintojo „Immucor“ reagentų kokybės sertifikatai išduodami kiekvienai prekių serijai.

UAB „Prosangvis“ direktorius

El. parašas

Valdas Petkevičius

Dokumentą elektroniniu
parašu pasirašė VALDAS
PETKEVIČIUS
Data: 2020-02-26 17:25:18



Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**IMMUCOR Europe
Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4000904/B
Original Approval: 8 December 2003
Current Certificate: 24 July 2018
Certificate Expiry: 23 July 2021

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom.



Lloyd's Register
LRQA

**EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 4000904/B SCHEDULE**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

**IMMUCOR Europe
Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany**

Annex II List A Products

immuClone Anti-A IgM and Galileo
immuClone Anti-B IgM and Galileo
immuClone Anti A,B IgM and Galileo
immuClone Anti-D rapid IgM and Galileo
immuClone Anti-D duo IgM + IgG and Galileo
immuClone Anti-CDE IgM + IgG and Galileo
immuClone (1) Anti-C IgM and Galileo
immuClone (1) Anti-c IgM and Galileo
immuClone (1) Anti-E IgM and Galileo
immuClone (1) Anti-e IgM and Galileo
immuClone (2) Anti-C IgM and Galileo
immuClone (2) Anti-c IgM and Galileo
immuClone (2) Anti-E IgM and Galileo
immuClone (2) Anti-e IgM and Galileo
immuClone Rh-Hr Control and Galileo
immuClone (1) Anti-K (Kell) IgM and Galileo
immuClone (2) Anti-K (Kell) IgM and Galileo
NOVACLONE Anti D IgM + IgG and Galileo
Automated immuClone Anti-K (Kell) Galileo IgM
immuClone Anti-D fast IgM and Galileo
Anti-K (Kell) quick

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom.



Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4000904/B SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

IMMUCOR Europe
Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

Annex II List B Products

immuClone Anti-Jk(a) IgM
Immucor Anti-Jk(b) IgM
Anti-Fy(a)
Anti-Fy(b)
Anti-Human Globulin Serum (Anti-IgG, -C3d) green
Anti-Jk(a) micro
Anti-Jk(b) micro
Anti-Fy(a) micro
Anti-Fy(b) micro
Negative Control micro

Schedule Issue: 01

Date of Schedule Issue: 24 July 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom.

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the In Vitro Diagnostic Medical Devices Directive 98/79/EC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex IV clause 4 of the Directive) undertake an EC Design Examination on the
stated products to ensure their conformity with the requirements of the Directive which apply to them.
The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER: **Immucor Medizinische Diagnostik GmbH**
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

PRODUCT NAME: **See Schedule**

PRODUCT DESCRIPTION: **In vitro diagnostic reagents, including control material, for
determining blood groups: ABO system, rhesus (C, c, D, E, e)
and K**

DESIGN DOSSIER REFERENCE: **03.TF.0001 Rev 002 – Technical File (IVDD List A)**

**This Certificate is not valid for products, the design or characteristics of which have been varied
from those examined. The manufacturer shall notify LRQA of any modification or changes to
the products in order to maintain a valid certificate.**

**This certificate's validity is subject to continued satisfactory completion of the verification of
manufactured product, as required by the Directive.**

Certificate No: 0088/4000904/00059

Original Approval: 8 December 2003

Current Certificate: 8 December 2018

Certificate Expiry: 7 December 2023

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

**EC DESIGN EXAMINATION CERTIFICATE
CERTIFICATE 0088/4000904/00059 SCHEDULE**

**Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany**

Product Name

immuClone Anti-A IgM
immuClone Anti-B IgM
immuClone Anti-A,B IgM
immuClone Anti-D rapid IgM and Galileo
immuClone Anti-D fast IgM
immuClone Anti-D duo IgM + IgG and Galileo
immuClone Anti-CDE IgM + IgG and Galileo
immuClone (1) Anti-C IgM and Galileo
immuClone (1) Anti-c IgM and Galileo
immuClone (1) Anti-E IgM and Galileo
immuClone (1) Anti-e IgM and Galileo
immuClone (2) Anti-C IgM and Galileo
immuClone (2) Anti-c IgM and Galileo
immuClone (2) Anti-E IgM and Galileo
immuClone (2) Anti-e IgM and Galileo
immuClone (1) Anti-K (Kell) IgM and Galileo
immuClone (2) Anti-K (Kell) IgM and Galileo
Automated immuClone Anti-K (Kell) Galileo IgM
Anti-K (Kell) quick
immuClone Rh-Hr Control and Galileo

This Schedule is only valid in association with the EC Design Examination certificate bearing the same number

Original Approval: 8 December 2003

Current Certificate: 8 December 2018

Certificate Expiry: 7 December 2023

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

**EC DESIGN EXAMINATION CERTIFICATE
CERTIFICATE 0088/4000904/00059 SCHEDULE**

**Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany**

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	8 December 2018	Certificate renewal. Job Number LRQ4000904/2173414

Certificate No: 0088/4000904/00059

Original Approval: 8 December 2003

Current Certificate: 8 December 2018

Certificate Expiry: 7 December 2023

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

Certificate of Approval

This is to certify that the Management System of:

Immucor Europe

IMMUCOR Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32, 63303 Dreieich, Germany

has been approved by LRQA to the following standards:

ISO 9001:2015



David Derrick - Area Operations Manager UK & Ireland

Issued By: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current Issue Date: 24 July 2018
Expiry Date: 22 July 2021
Certificate Identity Number: 10093927
Certificate Approval Number: LRQ 4000904

Original Approvals:
ISO 9001 – 30 November 2011

Approval Number(s): ISO 9001 – 00008327

The scope of this approval is applicable to:

Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Manufacturing, sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.



001

Certificate Schedule

Certificate Identity Number: 10093927

Locations	Activities
<p><u>Head Quarters</u> Immucor Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32, 63303 Dreieich, Germany</p>	<p>ISO 9001:2015 Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Manufacturing, sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.</p>
<p>Immucor S.L., Parc Technologic del Valles, C/Argenters, 7, Edif.II, Local cB, 08290 Cerdanyola del Vallès (Barcelona), Spain</p>	<p>ISO 9001:2015 Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.</p>
<p>Immucor France, 8, rue de la Croix Jarry, 75013 Paris, France</p>	<p>ISO 9001:2015 Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.</p>
<p>Immucor UK (also trading as, Quest Biomedical and IBG Immucor), 2 Cranbrook Way, Solihull Business Park, Solihull, B90 4GT, United Kingdom</p>	<p>ISO 9001:2015 Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.</p>



001

Certificate Schedule

Certificate Identity Number: 10093927

Locations

Activities

Immucor Italia S.p.a, Via Ettore Bugatti, 12,
20142 Milano, Italy

ISO 9001:2015

Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Immucor (Portugal) Diagnósticos Médicos Lda.,
TagusPark, Parque de Ciência e Tecnologia, Núcleo
Central, 333/335, 2740-0122 Oeiras,
Portugal

ISO 9001:2015

Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.



001

Immucor, Inc.

Declaration of Conformity – IVD Reagents

(In accordance with EN /ISO/IEC 170501:2010)
European Community Council Directive 98/79/EC

Immucor, Inc. hereby declares that the device(s) listed in appendix A comply with the UK Statutory Instrument 2002:618, of The Medical Devices Regulations 2002, transposing the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD). The List A and List B devices are in accordance with Annex IV (Full Quality Assurance) of the IVDD. The Self-Declared devices are in accordance with Annex III (EC Declaration of Conformity) of the IVDD.

Standards and Directives used in support of conformance to the In Vitro Diagnostic Medical Devices Directive 98/79/EC:

- EN ISO 13485:2012 - Quality management systems - Medical devices - Requirements for regulatory purposes [ISO 13485:2003]
- EN ISO 14971:2012 - Medical devices - Application of risk management to medical devices [ISO 14971:2007, Corrected Version 2007-10-01]
- EN 13612:2002/AC:2002 - Performance evaluation of in vitro diagnostic medical devices
- EN ISO 23640:2015 - *In vitro* diagnostic medical devices - Evaluation of stability of *in vitro* Diagnostic reagents [ISO 23640:2011]
- EN 13641:2002 - Elimination or reduction of infection related to in vitro diagnostic reagents
- ISO 14644-1:1999 - Cleanrooms and associated controlled environments - Classification of Air Cleanliness
- ISO 15223-1:2012 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 980:2008 - Symbols for use in the labelling of medical devices
- EN ISO 18113-1:2011 - In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements [ISO 15223-1:2009]
- EN ISO 18113-2:2011 - In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling). Part 2: In vitro diagnostic reagents for professional use [ISO 15223-2:2009]
- Regulation (EC) No 1272/2008 - on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 76/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

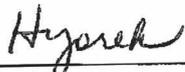
Manufacturer:

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia. 30071
USA
Phone: (770) 441-2051
Fax: (770) 441-3807

EC Authorized Representative:

Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
GERMANY
Phone: +49 (0) 6103-8056-0
Fax: +49 (0) 6103-8056-6390

This declaration is issued under the sole responsibility of Immucor, Inc.by:



Howard Yorek
Senior Director, Regulatory Affairs
Immucor, Inc.

Issue Date: 05 May 2017

**Appendix A: In Vitro Diagnostic Medical Devices
Declaration of Conformity
Immucor, Inc.**

**List A and List B devices in accordance with Annex IV (Full Quality Assurance)
of the IVDD**

Classification: Annex II, List A

corQC Test System
corQC EXTEND Standard
corQC EXTEND 1, 2, and 3
corQC EXTEND Complete
Weak D Cells
Referencells-4 (Group A₁, A₂, B, and O)
Referencells-2 (Group A₁ and B)
Referencells-1 (Group A₂)
WB corQC

Classification: Annex II, List B

Bovine Albumin Solution 22%
ImmuaAdd
pHix
Checkcell
Checkcell (Weak)
Panoscreen I and II
Panoscreen I, II and III
Hemantigen
Panocell-10
Panocell-16
Panocell-20
Panocell-10, Ficin-Treated
Capture-R Ready-Screen (I and II)
Capture-R Ready Screen (3)
Capture-R Ready-Screen (4)
Capture-R Ready-Screen (Pooled Cells)
Capture-R Ready-ID
Capture-R Ready-ID Extend I
Capture-R Ready-ID Extend II
Capture-CMV
Capture-R Ready Indicator Red Cells
Capture-CMV Indicator Red Cells
Capture LISS
Capture-R Positive Control Serum (Weak)
Capture-R Negative Control Serum
Capture-CMV Positive Control Serum (Weak)
Capture-CMV Negative Control Serum
Anti-Jk^a
Anti-Jk^b
Gamma PeG
Gamma-clone Anti-Human Globulin, Anti-IgG, -C3d;
Polyspecific (Murine Monoclonal)
Gamma-clone Anti-Human Globulin, Anti-IgG (Murine
Monoclonal)
Gamma-clone Anti- Jk^a (Monoclonal)
Gamma-clone Anti-Jk^b (Monoclonal)
Gamma-clone Anti-Fy^a (Monoclonal)

Conformity assessment for Annex IV and Annex II, List A and B devices performed by:

Lloyd's Register Quality Assurance Ltd (0088)
1 Trinity Park
Bickenhill Lane
Birmingham B37 7ES
United Kingdom
Phone: +44 24 7688 2309

Appendix A: In Vitro Diagnostic Medical Devices

Declaration of Conformity

Immucor, Inc.

**Self-Declared devices in accordance with Annex III (EC Declaration of Conformity)
of the IVDD**

Classification: Self Certify (Self-Declare), Annex III

Capture-P
Capture-P Ready-Screen
Platelet Wash and Storage Solution
Capture-P Indicator Red Cells
Capture-P Positive Control Serum (Weak)
Capture-P Negative Control Serum
Capture-R Select
Red Blood Cell (RBC) Storage Solution
W.A.R.M.
RESt
H.P.C.
Freeze-Dried Papain
Complement Control Cells
DAT Positive Control Cell
FMH RapidScreen
Fetal Bleed Screening
CMT Plates
Specimen Diluent
Anti-Di^a
Anti-k
Anti-Kp^a
Anti-Kp^b
Gamma-clone Anti-Le^a (Murine Monoclonal)
Gamma-clone Anti-Le^b (Murine Monoclonal)
Gamma-clone Anti-S (Monoclonal)
Gamma-clone Anti-s (Monoclonal)
Anti-S
Anti-s
Gamma EGA Kit
Gamma ELU-Kit II
Gamma Lectin System
Gamma Lewis Blood Group Substance
Gamma P1 Blood Group Substance
Gamma-Quin
GammaZyme-F

Declaration of Conformity

We Immucor Medizinische Diagnostik GmbH hereby declare that the products listed below 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.

In accordance to the In Vitro Diagnostic Medical Devices Directive 98/79/EC, the products have been designed and manufactured according to the following standards:

EN ISO 13485:2012	Medical Devices – Quality Management Systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical Devices-Application of risk management to medical devices.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640:2002	Stability testing of in vitro diagnostic reagent
EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
EN ISO 18113-2:2011	Information supplied by the manufacturer (labelling) with in vitro diagnostic reagents for professional use
ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 980:2008	Symbols for use in the labelling of medical devices

This declaration is issued under the sole responsibility of Immucor Medizinische Diagnostik GmbH. by

Issue Date: 15. Mar 2017



Signature
Name: Olga Pintschewa
Title: Quality Assurance Specialist

Manufacturer:
Immucor Medizinische
Diagnostik GmbH
Robert-Bosch-Str. 32
63303 Dreieich
GERMANY
Phone: +49-6103-8056-0
Fax: +49-6103-8056-199

List of Self-declare devices in accordance with Annex III of the In Vitro Diagnostic Medical Devices Directive 98/79/EC (EC Declaration of Conformity) of the IVDD.

Classification: Self Certify (Self-Declare), Annex III

Products	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	0009959
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-P(1) IgM	0008150
Anti-C ^w High Protein	0006605
Anti-Lu(a)	0008108
Anti-Lu(b)	0008109
Anti-IgM	0003003
Anti-IgA	0003002
Anti-Co(a)	0099100
Anti-Co(b)	0008307
Anti-Wr(a)	0099120
Anti-k (Cellano) (2)	0008055
Anti-Kp(a)	0007540
Anti-Kp(b)	0007550
Anti-Js(b)	0099140
Anti-S micro	0066304
Anti-s micro	0066305
Anti-k micro	0066306
Anti-C ^w micro	0066307



Anti-A hel	0005602
Anti-A(1) (Lectin)	0005405
Anti-A(1) (Lectin) Galileo	0066004
Anti-H (Lectin)	0005505
Galileo System Liquid Concentrate	0066056
Galileo Diluent	0066055; 0066058
Kleihauer Kit	0098100
Bromelin	0004110; 0004120
AB Serum, antibody free	0099301
Coombs Control Serum	0099430
immucor TP-12	0032001

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