

## **Declaration of Conformity acc. to Directive 98/79/EC**

Company name: ***IQ Products B.V.***  
Representative: C.M. Kebbedies  
Quality Assurance and Regulatory Affairs Manager  
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Herewith, IQ Products B.V. ensures and declares that:

- (1) The products listed below meet the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices which apply to the products;
- (2) The products concerned are produced at the manufacturing facility of IQ Products B.V. in conformance with the design control procedure requirements as specified in 98/79/EC and the records are available for review;
- (3) The products comply with all essential requirements of the Directive 98/79/EC on in vitro diagnostic medical devices.
- (4) IQ Products B.V. has a Quality System in place based on ISO13485:2003. The Quality System has been certified and the certificate has been issued by Notified Body on February 1<sup>st</sup>, 2016 and expires on February 1<sup>st</sup>, 2019.
- (5) IQ Products B.V. as company has fulfilled all obligatory and necessary requirements that are put forth by the European Directive 98/79/EC concerning the registration of in vitro diagnostic products, and therefore is allowed to market these products on the whole European market;

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IQ Products B.V.

February 4<sup>th</sup>, 2016



Christine M. Kebbedies  
Quality Assurance & Regulatory Affairs Manager

Product code	Productname	EDMS codes	EDMS term	GMDN code	GMDN term	CIP code
<b>SINGLES</b>	<b>FAMILY: monoclonal antibodies</b>					
IQP-126F	human CD1 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-126R	human CD1 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-100F	human CD2 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-100R	human CD2 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-519F	human CD3 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-519R	human CD3 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-519C	human CD3 Cy-Q	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-519A	human CD3 APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-535F	human CD4 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-535R	human CD4 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-535C	human CD4 Cy-Q	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-535A	human CD4 APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-103F	human CD5 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-103R	human CD5 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-127F	human CD7 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-127R	human CD7 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-104F	human CD8 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-104R	human CD8 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-104C	Human CD8 Cy-Q	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-104A	human CD8 APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-105F	human CD10 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-105R	human CD10 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-138F	human CD11b FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-138R	human CD11b R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-119R	human CD11c R-PE	130501.06	Antibodies for Lymphocyte typing	30616	Lymphocyte subtyping antibody kit	1395
IQP-112F	human CD13 FITC	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1059
IQP-112R	human CD13 R-PE	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1059
IQP-143F	human CD14 FITC	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1059

Product code	Productname	EDMS codes	EDMS term	GMDN code	GMDN term	CIP code
IQP-143R	human CD14 R-PE	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1059
IQP-143A	human CD14 APC	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1059
IQP-515F	human CD19 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-515R	human CD19 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-515C	human CD19 CyQ	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-515A	human CD19 APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-108F	Human CD20 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-108R	Human CD20 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-108A	Human CD20 APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-125F	human CD25 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-125R	human CD25 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-146R	human CD33 R-PE	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1059
IQP-144F	human CD34 FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-144R	human CD34 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-144A	human CD34 APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-124F	human CD45 FITC	130501.04	Antibodies for recognizing cell surface receptors	30614	Cell surface receptor recognizing antibody kit	1059
IQP-124R	human CD45 R-PE	130501.04	Antibodies for recognizing cell surface receptors	30614	Cell surface receptor recognizing antibody kit	1059
IQP-124C	human CD45 Cy-Q	130501.04	Antibodies for recognizing cell surface receptors	30614	Cell surface receptor recognizing antibody kit	1059
IQP-124A	human CD45 APC	130501.04	Antibodies for recognizing cell surface receptors	30614	Cell surface receptor recognizing antibody kit	1059
IQP-123F	human CD45RA FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-123R	human CD45RA R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-114R	human CD56 R-PE	130501.06	Antibodies for Lymphocyte typing	30616	Lymphocyte subtyping antibody kit	1395
IQP-111F	human CD103 FITC	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1483

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Product code	Productname	EDMS codes	EDMS term	GMDN code	GMDN term	CIP code
IQP-153F	human CD138 FITC	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1483
IQP-153R	human CD138 R-PE	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1483
IQP-153C	human CD138 Cy-Q	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1483
IQP-153A	human CD138 APC	130501.05	Antibodies for subtyping Leukemia (except B- & T-cell typing)	30615	Leukemia subtyping antibody kit	1483
IQP-191F	human IgG1 - FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-191R	human IgG1 - R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-191C	human IgG1 - CyQ	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-191A	human IgG1 - APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-192F	human IgG2a - FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-192R	human IgG2a - R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-192A	human IgG2a - APC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-193F	human IgG2b - FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-193R	human IgG2b - R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-194F	human IgM - FITC	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-194R	human IgM - R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-134F	human anti-HLA-DR FITC	130501.02	Antibodies for HLA class II determinants	30613	Human leukocyte antigen class II determinant antibody kit	1704
IQP-134R	human anti-HLA-DR R-PE	130501.02	Antibodies for HLA class II determinants	30613	Human leukocyte antigen class II determinant antibody kit	1704
IQP-134C	human anti-HLA-DR CyQ	130501.02	Antibodies for HLA class II determinants	30613	Human leukocyte antigen class II determinant antibody kit	1704
IQP-155F	human anti-MPO FITC	130501.01	Antibodies for HLA class II determinants	30613	Human leukocyte antigen class II determinant antibody kit	1704
<b>DUALS</b>	<b>FAMILY: monoclonal antibodies</b>					
IQP-253FR	human CD3 FITC/ human CD4 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-254FR	human CD3 FITC/ human CD8 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-249FR	human CD3 FITC/ human CD19 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-259FR	human CD4 FITC/ human CD8 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-264FR	human CD10 FITC/ human CD19 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-228FR	human CD45 FITC/ human CD14 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-268FR	human CD103 FITC/ human CD19 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910

Product code	Productname	EDMS codes	EDMS term	GMDN code	GMDN term	CIP code
IQP-227FR	human CD103 FITC/ human CD22 R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-291FR	IgG1FITC / IgG1R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-292FR	IgG1FITC / IgG2aR-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-294FR	IgG2aFITC / IgG1R-PE	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
<b>TRIPLES</b>						
<b>FAMILY: monoclonal antibodies</b>						
IQP-420FRC	CD4 FITC/CD8 R-PE/CD3 CyQ	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910
IQP-426FRC	IgG2aFITC / IgG1R-PE / IgG1 CyQ	130501.01	Antibodies for B- and T-cell subtyping	30611	B/T-cell subtyping antibody kit	1910

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