

DECLARATION OF CONFORMITY

Date of issue	Not applicable	Valid until	Not applicable
CE Assessment certificate	This products have been assessed on conformity according to the essential requirements as listed in Annex I of the European Directive 98/79/EC on in vitro diagnostic medical devices (IVDD). Certification by a Notified Body is not required.		
Certificate no.	Not applicable		

Product codes	As listed on page 3 and 4	Product names	As listed on page 3 and 4
EDMA code	13.05	EDMA term	Monoclonal Antibodies / Flow Cytometry
EMDN code Level 4	W010308	EMDN term	Monoclonal antibodies / Flow cytometry
GMDN code	56917	GMDN term	One or multiple immunoglobulins capable of binding to specific antigenic determinants and intended to be used for the qualitative and/or quantitative detection of multiple cluster of differentiation (CD) cell markers in a clinical specimen, including associated percentage and/or enumeration of specific cell populations.

Manufacturer name and Address	IQ Products BV, Rozenburglaan 13a, 9727 DL Groningen, The Netherlands		
Single Registration number (SRN)	NL-MF-000010812		
Competent Authority	Dutch Health Care Inspectorate CIBG, registration no. NL-CA002-24461		
Harmonized Standards Referenced	<ul style="list-style-type: none"> • EN ISO 13485:2016 • EN 13641:2002 • EN 13612:2002 • EN 13975:2003 • EN ISO 14971:2012 	<ul style="list-style-type: none"> • EN ISO 18113-1:2011 • EN ISO 18113-2:2011 • EN ISO 23640:2015 • EN ISO 15223-1:2021 	
Other regulations/standards by which the product is regulated	Regulation (EC) No. 1272/2008; Regulation (EU) No. 453/2010; Regulation (EU) No. 2015/830.		

This declaration of conformity is issued under the sole responsibility of IQ Products BV.

- (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 BV in conformance with the design control procedure requirements as specified in Directive 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 BV has a Quality System in place based on ISO 13485:2016. The Quality System has been certified and the certificate has been issued by Notified Body DEKRA Certification BV (Identification number 0344) on February 01, 2022 and expires on February 01, 2025;
- (5) IQ Products BV has been registered as manufacturer of In Vitro Diagnostic medical devices with the Dutch Health Care Inspectorate CIBG, registration no. NL/CA/3024519 and with the FDA, registration no. 9681582;
- (6) IQ Products BV 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 medical devices, and therefore is allowed to manufacture and supply these products on the Dutch market and on the markets of the other Member States of the European Union, and be exported to non-EU Member States.

We hereby certify that as of the date of this declaration, the product described above conform with the provisions of the European Directive 98/79/EC on in vitro diagnostic medical devices (IVDD). All supporting documentation is retained at IQ Products BV.

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Date: 14 February 2022

Place: Groningen, the Netherlands

Signature: 

Name: Christine M. Kebbedies

Function: Manager QA & RA

Company: IQ Products BV

Product code	Product name
SINGLES	
IQP-126F	human CD1a FITC
IQP-126R	human CD1a R-PE
IQP-100F	human CD2 FITC
IQP-100R	human CD2 R-PE
IQP-519F	human CD3 FITC
IQP-519R	human CD3 R-PE
IQP-519C	human CD3 Cy-Q
IQP-519A	human CD3 APC
IQP-535F	human CD4 FITC
IQP-535R	human CD4 R-PE
IQP-535C	human CD4 Cy-Q
IQP-535A	human CD4 APC
IQP-103F	human CD5 FITC
IQP-103R	human CD5 R-PE
IQP-127F	human CD7 FITC
IQP-127R	human CD7 R-PE
IQP-104F	human CD8 FITC
IQP-104R	human CD8 R-PE
IQP-104C	Human CD8 Cy-Q
IQP-104A	human CD8 APC
IQP-105F	human CD10 FITC
IQP-105R	human CD10 R-PE
IQP-138F	human CD11b FITC
IQP-138R	human CD11b R-PE
IQP-119R	human CD11c R-PE
IQP-112F	human CD13 FITC
IQP-112R	human CD13 R-PE
IQP-143F	human CD14 FITC
IQP-143R	human CD14 R-PE
IQP-143A	human CD14 APC
IQP-515F	human CD19 FITC
IQP-515R	human CD19 R-PE
IQP-515C	human CD19 CyQ
IQP-515A	human CD19 APC
IQP-108F	Human CD20 FITC
IQP-108R	Human CD20 R-PE
IQP-108A	Human CD20 APC
IQP-125F	human CD25 FITC
IQP-125R	human CD25 R-PE
IQP-146R	human CD33 R-PE
IQP-144F	human CD34 FITC
IQP-144R	human CD34 R-PE
IQP-144A	human CD34 APC

Product code	Product name
IQP-124F	human CD45 FITC
IQP-124R	human CD45 R-PE
IQP-124C	human CD45 Cy-Q
IQP-124A	human CD45 APC
IQP-123F	human CD45RA FITC
IQP-123R	human CD45RA R-PE
IQP-114R	human CD56 R-PE
IQP-111F	human CD103 FITC
IQP-153F	human CD138 FITC
IQP-153R	human CD138 R-PE
IQP-153C	human CD138 Cy-Q
IQP-153A	human CD138 APC
IQP-191F	human IgG1 - FITC
IQP-191R	human IgG1 - R-PE
IQP-191C	human IgG1 - CyQ
IQP-191A	human IgG1- APC
IQP-192F	human IgG2a - FITC
IQP-192R	human IgG2a - R-PE
IQP-192A	human IgG2a - APC
IQP-193F	human IgG2b - FITC
IQP-193R	human IgG2b - R-PE
IQP-194F	human IgM - FITC
IQP-194R	human IgM - R-PE
IQP-134F	human anti-HLA-DR FITC
IQP-134R	human anti-HLA-DR R-PE
IQP-134C	human anti-HLA-DR CyQ
IQP-155F	human anti-MPO FITC
DUALS	
IQP-253FR	human CD3 FITC/ human CD4 R-PE
IQP-254FR	human CD3 FITC/ human CD8 R-PE
IQP-249FR	human CD3 FITC/ human CD19 R-PE
IQP-259FR	human CD4 FITC/ human CD8 R-PE
IQP-264FR	human CD10 FITC/ human CD19 R-PE
IQP-228FR	human CD45 FITC/ human CD14 R-PE
IQP-268FR	human CD103 FITC/ human CD19 R-PE
IQP-227FR	human CD103 FITC/ human CD22 R-PE
IQP-291FR	IgG1FITC / IgG1R-PE
IQP-292FR	IgG1FITC / IgG2aR-PE
IQP-294FR	IgG2aFITC / IgG1R-PE
TRIPLES	
IQP-420FRC	CD4 FITC/CD8 R-PE/CD3 CyQ
IQP-426FRC	IgG2aFITC / IgG1R-PE / IgG1 CyQ