DECLARATION OF CONFORMITY

Date of issue	Not applicable	**Valid until**	Not applicable
CE Assessment certificate	This product has 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 code	IQP-363	**Product name**	Fetal Cell Count™ Kit
EDMA code	130190.90	**EDMA term**	Other Hematology Reagents
EMDN code Level 4	W010301	**EMDN term**	Hematology reagents
GMDN code	55975	**GMDN term**	Foeto-maternal haemorrhage/ Kleihauer test IVD, kit, fluorescent activated cell sorting/flow cytometry (FACS/Flow)
Basic UDI - DI	87179530223IQP-363NG		
Intended use	The Fetal Cell Count™ Kit is intended for the discrimination and quantitative detection of human fetal red blood cells (fRBC) in maternal blood. This method used for diagnosis of Fetomaternal Hemorrhage (FMH) is applied to peripheral blood samples of pregnant women with abdominal trauma and/or suspected Rhesus D (RhD) incompatibility. The Fetal Cell Count™ Kit is based on a sensitive and accurate, non-automated flow cytometric method, which offers a dual fluorescent detection of two intracellular antigens, fetal hemoglobin (HbF) and carbonic anhydrase (CA). Both HbF and CA are detected in red blood cells obtained from EDTA anti-coagulated or heparin-treated human peripheral whole blood. The complete dual-color staining and analysis of up to 5 samples, that must be executed and interpreted by well-trained and authorized laboratory technicians, can be concluded within 90 minutes from blood collection.		

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-CA002-24455
Harmonized Standards Referenced	• EN ISO 13485:2016 • EN 13641:2002 • EN 13612:2002 • EN 13975:2003 • EN ISO 14971:2012 • EN ISO 18113-1:2011 • EN ISO 18113-2:2011 • EN ISO 23640:2015 • EN ISO15223-1:2021
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 product meet the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices which apply to the products;

(2) The Fetal Cell Count™ Kit is placed on the market for the first time in 2002;

(3) The product concerned is produced at the manufacturing facility of IQ Products B.V. in conformance with the design control procedure requirements as specified in Directive 98/79/EC and the records are available for review;

(4) The product comply with all essential requirements of the Directive 98/79/EC on in vitro diagnostic medical devices;

(5) 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 B.V. (Identification number 0344) on February 01, 2022 and expires on February 01, 2025;

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.

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

Date: 2 February 2022

Place: Groningen, the Netherlands

Signature: _____

Name: Christine M. Kebbedies

Function: Manager QA & RA

Company: IQ Products BV.