

**Declaration of Conformity
acc. to Directive 98/79/EC – Annex IV**

Company name: ***IQ Products B.V.***
 Adress: Rozenburglaan 13a
 9727 DL Groningen
 The Netherlands
 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 Fetal Cell Count™ kit (Product code: IQP-363) meet the provisions of the European Directive 98/79/EC on In Vitro Diagnostic medical devices which apply to the product;
- (2) The Fetal Cell Count™ kit is produced at the manufacturing facility of IQ Products B.V. in conformance with the design control procedure requirements as specified in the Directive 98/79/EC and the records are available for review;
- (3) The Fetal Cell Count™ kit complies 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 ISO13485:2016. The Quality System has been certified and the certificate has been issued by Notified Body DEKRA Certification B.V. (Identification number 0344) on February 1st, 2019 and expires on February 1st, 2022;
- (5) IQ Products 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 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 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.

Product code	Product name	EDMA code	EDMA term
IQP-363	Fetal Cell Count™ Kit	130190.90	Other Hematology Reagents
		GMDN code	GMDN term
		55975	Foeto-maternal haemorrhage/Kleihauer test IVD, kit, fluorescent activated cell sorting/flow cytometry (FACS/Flow)
Device Classification according to IVD Directive 98/79/EC			
Other/General Device			

IQ Products B.V.

January 29th, 2019



Christine M. Kebbedies
 Manager Quality Assurance & Regulatory Affairs