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
E-mail: c.kebbedies@iqproducts.nl

Herewith, IQ Products B.V. ensures and declares that:

(1) The FMH QuikQuant (Product code: QQF-100) meet the provisions of the European Directive 98/79/EC on In Vitro Diagnostic medical devices which apply to the product;

(2) The FMH QuikQuant 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 FMH QuikQuant 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**
QQF-100	FMH QuikQuant	130102.02	Hemoglobin subtypers HbA2, HbF, HbS, etc. (excl. HbA1)
		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