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 HIT*Alert*™ kit (Product code: IQP-396) meet the provisions of the European Directive 98/79/EC on in vitro diagnostic medical devices which apply to the product;

(2) The HIT*Alert*™ 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 HIT*Alert*™ 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 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;

(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-396	HIT*Alert*™ Kit	130204.90	Other Primary Hemostasis/Platelet Factors
		GMDN code	**GMDN term**
		61512	Platelet factor 4-heparin complex total antibody IVD, kit, agglutination, rapid
	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