

**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 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 CMV Brite™ and the CMV Brite™ Turbo kits are placed on the market for the first time in 1995 resp. 1999;
- (3) The products concerned are produced at the manufacturing facility of IQ Products B.V. in conformance with the design control procedure requirements as specified in 98/79/EC and the records are available for review;
- (4) The products comply with all essential requirements of the Directive 98/79/EC on in vitro diagnostic medical devices;
- (5) 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;
- (6) 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;
- (7) 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 market these products on the whole European market;

IQ Products B.V.

January 29th, 2019



Christine M. Kebbedies
Manager Quality Assurance & Regulatory Affairs

Directive 98/79EC, Annex II – list B
Notified Body No. 0344

Product code	Product name	EDMA codes	EDMA term	GMDN code	GMDN term
VIR-CMV110	CMV Brite™ Turbo Kit	150402.90	Other CMV Reagents	49707	Cytomegalovirus (CMV) antigen IVD, kit, fluorescent immunoassay
VIR-CMV100	CMV Brite™ Antigenemia Detection Kit	150402.90	Other CMV Reagents	49707	Cytomegalovirus (CMV) antigen IVD, kit, fluorescent immunoassay
VIR-CMVC10/C11	C10/C11 cocktail anti-CMV	150402.05	CMV IgG	49710	Cytomegalovirus (CMV) antigen IVD, Reagent
VIR-C10/C11	C10/C11 cocktail anti-CMV	150402.05	CMV IgG	49710	Cytomegalovirus (CMV) antigen IVD, Reagent
VIR-FITC	FITC conjugate sheep anti-mouse	150402.90	Other CMV Reagents	49710	Cytomegalovirus (CMV) antigen IVD, Reagent
VIR-CMV CS05	Control slides (5x)	150402.90	Other CMV Reagents	49710	Cytomegalovirus (CMV) antigen IVD, Reagent