DECLARATION OF CONFORMITY

Date of issue	2022-02-01	**Valid until**	2025-05-26
CE Assessment certificate	This product has been assessed on conformity and certified by the Notified Body DEKRA Certification B.V. according to the European Directive 98/79/EC on in vitro diagnostic medical devices (IVDD), Annex II – list B.		
Certificate no.	2114129CE01		

Product codes	VIR-CMV110 VIR-CMVC10/C11 VIR-FITC VIR-CMV CS05	**Product name**	CMV Brite™ Turbo kit C10/C11 cocktail anti-CMV FITC conjugate sheep anti-mouse Control slides (5x)
EDMA codes	150402.90 150402.05	**EDMA terms**	Other CMV Reagents CMV IgG
GMDN codes	49707 47710	**GMDM terms**	Cytomegalovirus (CMV) antigen IVD, kit, fluorescent immunoassay. Cytomegalovirus (CMV) antigen IVD, reagent.
Intended use	The CMV Brite™ Turbo kit uses the well-defined C10/C11 antibody cocktail to detect the CMV lower matrix phosphoprotein (pp65), an early antigen in virus replication, which is abundantly present in antigen-positive polymorphonuclear cells. The CMV Brite™ Turbo kit, CMV pp65 antigenemia assay, is a valuable tool in the diagnosis and monitoring of active CMV infection.		

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/CA/3024519
Notified Body	DEKRA Certification B.V. Identification number 0344
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 ISO 15223-1:2021
Other regulations/standards by which the product is regulated	Regulation (EC) No. 1272/2008; Regulation (EU) No. 453/2010; Regulation (EU) No. 2015/830.

(1) The products meet the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices which apply to the products;

(2) The CMV Brite™ Turbo kit is placed on the market for the first time in 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 Directive 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 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;

(6) IQ Products is registered as manufacturer of In Vitro Diagnostic medical devices with the Dutch Health Care Inspectorate CIBG, registration no. NL/CA/3024519 and with the Food and Drug Administration FDA, registration no. 9681582;

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: February 2, 2022

Place: Groningen, the Netherlands

Signature: C. Kebbedies

Name: Christine M. Kebbedies

Function: Manager QA & RA

Company: IQ Products BV.