Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	IQ Products
Manufacturer address and contact details	Rozenburglaan 13a 9727 DL Groningen The Netherlands
Single Registration Number (SRN)	NL-MF-000010812

Authorised Representative name	Not applicable
Authorised Representative contact details	Not applicable
Single Registration Number (SRN)	Not applicable

Notified body name	DEKRA Certification B.V.
Notified body number	0344
Directive Certificate number(s) to which this confirmation is made	2114129CN
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity	26 May 2025
End date of extended validity/transition period	31 Dec 2027 NOTE: This transitional period applies only when the DEKRA Certification and IQ Products have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of the Regulation (EU) 2024/1860 no later than 26 September 2026.

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

Devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☒ 26 May 2026 for class C devices

☒ 27 May 2027 for class B and class A (sterile) devices

☒ Signed written agreement(s) will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☒ 26 September 2026 for class C devices

☒ 27 September 2027 for class B and class A (sterile) devices

☒ We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.

➢ **Directive Certificate(s)** as listed above or in the attached schedule

Directive Certificate covering the device(s) listed in the attached schedule was issued after 25 May 2017, was valid on 26 May 2022 and has not been withdrawn afterwards.

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

➢ **Quality Management System (QMS)**

QMS in accordance with Article 10(8) IVDR is in place.

➢ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	IVDR Device Class	End date of extended validity / transition period	Directive Certificate number to which this declaration is issued	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged/contract signed
CMV Brite Turbo Kit (VIR-CMV 110) CMV Control slides (VIR-CMV CS05) FITC conjugate (VIR-FITC) CMV C10/C11 cocktail (VIR-CMV C10/C11)	C	31 Dec 2027	2114129CN	26 May 2025	DEKRA Certification B.V. 0344	DEKRA Certification B.V. 0344
Fetal Cell Count Kit (IQP-363)	C	31 Dec 2028	Not applicable	Not applicable	Not applicable	DEKRA Certification B.V. 0344
FMH QuikQuant (QQF-100)	C	31 Dec 2028	Not applicable	Not applicable	Not applicable	DEKRA Certification B.V. 0344
HIT*Alert* Kit (IQP-396)	C	31 Dec 2028	Not applicable	Not applicable	Not applicable	Not applicable yet
Family/Group Monoclonal Antibodies (MoAbs)	B	31 Dec 2029	Not applicable	Not applicable	Not applicable	Not applicable yet

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

Family/Group of Monoclonal Antibodies

Product code	Product name
IQP-134C	human anti-HLA-DR CyQ
IQP-134F	human anti-HLA-DR FITC
IQP-134R	human anti-HLA-DR R-PE
IQP-155F	human anti-MPO FITC
IQP-126F	human CD1 FITC
IQP-126R	human CD1 R-PE
IQP-105F	human CD10 FITC
IQP-264FR	human CD10 FITC/ human CD19 R-PE
IQP-105R	human CD10 R-PE
IQP-111F	human CD103 FITC
IQP-268FR	human CD103 FITC/ human CD19 R-PE
IQP-227FR	human CD103 FITC/ human CD22 R-PE
IQP-138F	human CD11b FITC
IQP-138R	human CD11b R-PE
IQP-119R	human CD11c R-PE
IQP-112F	human CD13 FITC
IQP-112R	human CD13 R-PE
IQP-153A	human CD138 APC
IQP-153C	human CD138 Cy-Q
IQP-153F	human CD138 FITC
IQP-153R	human CD138 R-PE
IQP-143A	human CD14 APC
IQP-143F	human CD14 FITC
IQP-143R	human CD14 R-PE
IQP-515A	human CD19 APC
IQP-515C	human CD19 CyQ
IQP-515F	human CD19 FITC
IQP-515R	human CD19 R-PE
IQP-100F	human CD2 FITC
IQP-100R	human CD2 R-PE
IQP-108A	Human CD20 APC
IQP-108F	Human CD20 FITC
IQP-108R	Human CD20 R-PE
IQP-125F	human CD25 FITC
IQP-125R	human CD25 R-PE
IQP-519A	human CD3 APC
IQP-519C	human CD3 Cy-Q
IQP-519F	human CD3 FITC
IQP-253FR	human CD3 FITC/ human CD4 R-PE
IQP-254FR	human CD3 FITC/ human CD8 R-PE
IQP-249FR	human CD3 FITC/human CD19 R-PE
IQP-519R	human CD3 R-PE
IQP-146R	human CD33 R-PE
IQP-144A	human CD34 APC

IQP-144F	human CD34 FITC
IQP-144R	human CD34 R-PE
IQP-535A	human CD4 APC
IQP-535C	human CD4 Cy-Q
IQP-535F	human CD4 FITC
IQP-420FRC	human CD4 FITC/ CD8 R-PE/ CD3 CyQ
IQP-259FR	human CD4 FITC/ human CD8 R-PE
IQP-535R	human CD4 R-PE
IQP-124A	human CD45 APC
IQP-124C	human CD45 Cy-Q
IQP-124F	human CD45 FITC
IQP-228FR	human CD45 FITC/ human CD14 R-PE
IQP-124R	human CD45 R-PE
IQP-123F	human CD45RA FITC
IQP-123R	human CD45RA R-PE
IQP-103F	human CD5 FITC
IQP-103R	human CD5 R-PE
IQP-114R	human CD56 R-PE
IQP-127F	human CD7 FITC
IQP-127R	human CD7 R-PE
IQP-104A	human CD8 APC
IQP-104C	Human CD8 Cy-Q
IQP-104F	human CD8 FITC

IQP-104R	human CD8 R-PE
IQP-191C	human IgG1 - CyQ
IQP-191F	human IgG1 - FITC
IQP-191R	human IgG1 - R-PE
IQP-191A	human IgG1- APC
IQP-192A	human IgG2a - APC
IQP-192F	human IgG2a - FITC
IQP-192R	human IgG2a - R-PE
IQP-193F	human IgG2b - FITC
IQP-193R	human IgG2b - R-PE
IQP-194F	human IgM - FITC
IQP-194R	human IgM - R-PE
IQP-291FR	IgG1FITC / IgG1R-PE
IQP-292FR	IgG1FITC / IgG2aR-PE
IQP-294FR	IgG2aFITC / IgG1R-PE
IQP-426FRC	IgG2aFITC / IgG1R-PE / IgG1 CyQ