

Declaration of Conformity

We Virotech Diagnostics GmbH
Waldstrasse 23 A2
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

Enterovirus IgG ELISA

Order No.: EC116G00CD

is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures acc. to **Annex III (2-5)**.

Dietzenbach 2022-05-25



Rodrigo Berlie
Managing Director

Next verification of this Declaration of Conformity is scheduled for 2023-05-25 at the latest.

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We Virotech Diagnostics GmbH
Waldstrasse 23 A2
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product


Enterovirus IgA ELISA

Order No.: EC116A00CD

is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures acc. to **Annex III (2-5)**.

Dietzenbach 2022-05-25



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We Virotech Diagnostics GmbH
Waldstrasse 23 A2
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

Enterovirus IgM ELISA

Order No.: EC116M00CD

is in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures acc. to **Annex III (2-5)**.

Dietzenbach 2022-05-25



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