CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the ELISA product

SARS-CoV-2 NeutraLISA *EI 2606-9601-4*
(product name, order number)

meets the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

- Member of the Board - - Head of Quality Management -

CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the ELISA product

Anti-SARS-CoV-2 QuantiVac ELISA (IgG) *EI 2606-9601-10 G*
(product name, order number)

meets the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

(Place and date of issue)

Susanne Aleksandrowicz
- Member of the Board -

Dr. Ewald Müller-Ruchholtz
- Head of Quality Management -

CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the ELISA product

Anti-SARS-CoV-2 ELISA (IgA) *EI 2606-9601 A*
(product name, order number)

meets the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

- Member of the Board - - Head of Quality Management -

CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the ELISA product

Anti-SARS-CoV-2 ELISA (IgG) *EI 2606-9601 G*
(product name, order number)

meets the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

(place and date of issue)

- Member of the Board -

- Head of Quality Management -

CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the products

EUROIMMUN Analyzer I	*YG 0014-0101*
Conductive disposable tips (300 µl)	*ZG 0201-0118*
Conductive disposable tips (1100 µl)	*ZG 0202-0110*

(product name, order number)

meet the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and its transpositions in national laws which apply to it.

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

(Place and date of issue)

Dr. Ewald Müller-Kunert
- Head of Quality Management -

Susanne Aleksandrowicz
- Member of the Board -