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Declaration of Conformity

Regulation (EU) 2017/746 of the European parliament and of the council (IVDR)

Manufacturer:	**IMMUCOR Medizinische Diagnostik GmbH** Robert-Bosch-Strasse 32 63303 Dreieich Germany
Single Registration Number	DE-MF-000006494
QM Certificate Registration Number	SX 1191616-1

IMMUCOR Medizinische Diagnostik GmbH, hereby declares that the device(s) listed in Appendix A meet the provisions of regulation (EU) 2017/746 on in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. The devices are classified as Class A devices and are in accordance with the requirements set out in regulation (EU) 2017/746.

Standards and Directives used in support of conformance to regulation (EU) 2017/746 on in vitro diagnostic medical devices:

EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for regulatory purposes.
EN ISO 14971:2019	Medical Devices- Application of risk management to medical devices.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61010-2-020:2016	Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 2-020: Particular requirements for laboratory centrifuges
EN IEC 61326-1:2013	Electrical equipment for measurement, control and laboratory use – Part 1: General Requirements
EN IEC 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – Part 2-6: Particular Requirements
EN ISO 17511:2020	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
IEC 62304:2006	Medical device software — Software life cycle processes
Directive 2011/65/EU	On the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive 2011/65/EU (RoHS 2)	On the restriction of the use of certain hazardous substances in electrical and electronic equipment
EU Directive 2015/863 (RoHS 3)	On the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive 2014/30/CE	Electromagnetic Compatibility (EMC)
Directive 2012/19/EU	On Waste Electrical and Electronic Equipment (WEEE)
Regulation (EC) No 1907/2006 (REACH)	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

This declaration is issued under the sole responsibility of Immucor Medizinische Diagnostik GmbH by

Place, date of issue: Dreieich, 20-Dec-2023

DocuSigned by Maria Wilhelmi
Maria Wilhelmi | I approve this document
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Maria Wilhelmi
RA/ QA/ PRRC
IMMUCOR Medizinische Diagnostik GmbH

Classification: Class A

Products	Product Number(s)	Basic UDI-DI	Intended Use
Galileo NEO	0064600	88823405W0202030102A52HY	The NEO instrument platform is designed to automate standard immunohematology assays using a microplate-based platform. Assays include ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping and antigen screening.
NEO Iris	0064598	88823405W0202030102A52HY	