EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX

TÜVRheinland®

Registration No.: IX 1191616-2

Manufacturer:
IMMUCOR
Medizinische Diagnostik GmbH
Robert-Bosch-Str. 32
63303 Dreieich
Germany

EUDAMED Single Registration No.: DE-MF-000006494

General product group name: Products of class D

HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVR 0106: Other devices intended to be used for blood grouping
W0103030499 - IMMUNOHAEMATOLOGY (BLOOD GROUPING) TESTS - OTHER

Product name: immuClone Rh-Hr Control - REF 0006720, 0006721
Models and types: immuClone Rh-Hr Control Galileo - REF 0066006, 0066083

Basic UDI-DI: 88823405W0103030499D48QB

Intended use: immuClone® Rh-Hr Control and immuClone® Rh-Hr Control Galileo are Blood Group Controls used for parallel testing with immuClone® IgM monoclonal Blood Grouping antisera to indicate if the antisera could give a false positive result due to abnormalities of the sample such as autoantibodies, positive direct antiglobulin test or protein abnormalities. For Manual Tube, Slide, Microplate and Automated Microplate Tests (qualitative). immuClone® Rh-Hr Control is intended for Manual Tube, Slide and Microplate Tests (qualitative). immuClone® Rh-Hr Control Galileo is intended for Automated Microplate Tests (qualitative).

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.: 1120776-20

Effective date: 2023-09-13

Expiry date: 2028-09-12

Issue date: 2023-09-13

TÜV Rheinland LGA Products GmbH TÜVRheinland

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.

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Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-09-13

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TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Katja Mierisch
TÜV Rheinland LGA Products GmbH
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