EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1804154-1
Manufacturer:	BioArray Solutions Ltd. 35 Technology Drive Suite 100 Warren NJ 07059 USA
EUDAMED Single Registration No.:	US-MF-000022068
Products:	Products of class C HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0201 Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration W01030403 - HLA ANTIGEN TYPING IVR 0202 Other devices intended to be used for tissue typing W01030499 TISSUE TYPING REAGENTS - OTHER
Authorized representative(s):	Immucor Medizinische Diagnostik GmbH

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.
If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.
If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.:	1092511-40
Effective date:	2025-05-22
Expiry date:	2030-03-16
Issue date:	2025-05-22

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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	Robert-Brosch-Strasse 32, 63303 Dreieich, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-03-17
1	Correction, Scope extension IVR 0202	2025-05-22

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