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 2333083-1
Manufacturer:	Immunodiagnostic Systems Limited 10 Didcot Way Boldon Business Park, Boldon Tyne & Wear NE35 9PD United Kingdom
EUDAMED Single Registration No.:	GB-MF-000015851
Products:	Products of class B: IMMUNOCHEMISTRY (IMMUNOLOGY) IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease EMDN: W01020602 RENAL METABOLISM ASSAYS EMDN: W01021522 STANDARDS AND CALIBRATORS IMMUNOCHEMISTRY EMDN: W01021520 CONTROLS – IMMUNOCHEMISTRY EMDN: W01020604 ENDOCRINE HORMONES AND PEPTIDES EMDN: W01020603 BONE AND MINERAL METABOLISM ASSAYS IMMUNOCHEMISTRY (IMMUNOLOGY) IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers EMDN: W01020603 BONE AND MINERAL METABOLISM ASSAYS

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.:	84976391-10
Effective date:	2024-06-25
Expiry date:	2028-08-26
Issue date:	2024-06-25

Daniel Świątko
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
www.zlg.de
BS-MDR-091

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Authorized representative(s):	Immunodiagnostic Systems S.A. Rue Ernest Solvay 101 4000 Liege, Belgium BE-AR-000015342

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2023-08-27
2	Scope extension	2023-10-30
3	Scope extension	2024-06-25

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