EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapters I and III

Registration No.:	HX 1530337-1
Manufacturer:	OPERON S.A. Camino del Plano, 19 50410 Cuarte de Huerva (Zaragoza) Spain
EUDAMED Single Registration No.:	ES-MF-000004790
Products:	Products of class B: INFECTIOUS DISEASES IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents W01050116 - OTHER BACTERIOLOGY - NA REAGENTS W01050703 - MULTIPLE VIRUSES PANELS W01050808 - CONTROLS - INFECT. IMMUNOLOGY W01050901 - BACTERIOLOGY - RT & POC W01050904 - PARASITOLOGY RT & POC W01050906 - MULTIPLE PATOGENS - RT & POC W01050990 - OTHER VIROLOGY RT & POC

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.:	92875154-20
Effective date:	2026-02-19
Expiry date:	2029-12-18
Issue date:	2026-02-19

Marta Trzpil
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 in vitro diagnostic medical devices with the identification number 0197.

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

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Precisely Right.

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Registration No.: HX 1530337-1

Manufacturer: OPERON S.A.
Camino del Plano, 19
50410 Cuarte de Huerva (Zaragoza)
Spain

EUDAMED Single Registration No.: ES-MF-000004790

IMMUNOCHEMISTRY (IMMUNOLOGY)
IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers
W01021520 - CONTROLS - IMMUNOCHEMISTRY
W01021601 - SPECIFIC PROTEINS RT & POC

Products of class C:

GENETIC TESTING
IVR 0403 Other devices intended to be used for human genetic testing
W01060104 POLYMORPHISMS

Authorized representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-12-19
1	Correction and Scope extension Products of class C	2025-04-16
2	Scope extension of EMDN W01050703 and EMDN W01050906 of Products of class B	2026-02-19

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