

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1530337-1

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

Scope: Design and development, manufacture and distribution of in-vitro diagnostic medical devices used in the determination and diagnosis of pathogens, disease status, genetic testing, HLA associated diseases, prostate specific antigen, typing of HLA and Chlamydia detection.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

