

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Medlumics S.L.
Plaza de la Encina
10-11 Núcleo 3-2A
28760 Tres Cantos
Madrid
Spain

Holds Certificate Number: MD 661449

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development and manufacturing of Optical Coherence Reflectometry (OCR) medical systems for use in ablation procedures and characterization of tissues. Provision of specialized technology consultancy services for medical devices based on integrated optics and photonics.

Diseño, desarrollo y fabricación de sistemas médicos de Reflectometría de Coherencia Óptica (RCO) para su uso en procedimientos de ablación y caracterización de tejidos. Provisión de servicios de consultoría tecnológica especializada para equipos médicos basados en óptica integrada y fotónica.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2015-09-04

Latest Revision Date: 2024-09-03

Effective Date: 2024-09-04

Expiry Date: 2027-09-03



Page: 1 of 1

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