

**CERTIFICATE N.
CERTIFICADO N. 0620.2025**

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY
CERTIFICA QUE EL SISTEMA DE GESTIÓN DE CALIDAD DE

**BIOCERAMED
Cerâmicos para Aplicações Médicas S.A.**

AVEPARK - PARQUE DE CIENCIA E TECNOLOGIA Z.I. DA GANDRA, BARCO –
4805-017 GUIMARAES PORTUGAL

OPERATIVE UNITS / *INSTALACIÓN DE*

AVEPARK - PARQUE DE CIENCIA E TECNOLOGIA Z.I. DA GANDRA, BARCO –
4805-017 GUIMARAES PORTUGAL

IS IN COMPLIANCE WITH THE STANDARD / *REÚNE LOS REQUISITOS DE LA NORMA*

EN ISO 13485:2016/A11:2021

FOR THE FOLLOWING ACTIVITIES / *PARA LAS SIGUIENTES ACTIVIDADES*

Design, development, and manufacturing of medical devices, including non-active orthopedic implants (Bone grafts, Injectable Bone substitutes and bone cements), and implants incorporating animal-derived tissues. Sales and distribution of hyaluronic acid injectables, devices for autologous preparation and separation, soft tissue implants, and dental membranes for medical use. Bioceramics production and sale (calcium phosphates, Hydroxyapatite and Bioglass): raw material for medical use

Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma ISO 13485:2016, puede obtenerse consultando a la organización

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
*EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO
PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN*

DATE:	FIRST CERTIFICATION <i>PRIMERA CERTIFICACIÓN</i>	CURRENT ISSUE <i>EMISION ACTUAL</i>	EXPIRY <i>VÁLIDO HASTA</i>
	2025-05-19	2025-05-19	2028-05-18



IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years
La validez del certificado está sujeta a auditorías anuales y a la recertificación completa del Sistema de Gestión con una periodicidad trienal



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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.