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**CERTIFICATE N. 9124.LCH2**  
**CERTIFICADO N.**

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

**LINEAR CHEMICALS, S.L.U.**

C/JOAQUIM COSTA 18 2° PLANTA - 08390 MONTGAT (BARCELONA) - SPAIN

OPERATIVE UNITS / INSTALACIÓN DE



C/JOAQUIM COSTA 18 2° PLANTA - 08390 MONTGAT (BARCELONA) - SPAIN

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

**ISO 13485:2016**

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES

*Design, development, manufacturing and trading of medical devices for in vitro diagnosis. Import and distribution of sterile set of infusion and syringe. Design, development, manufacturing, technical assistance and trading of medical devices for in vitro diagnosis.*

*Diseño, desarrollo, fabricación y comercialización de producto sanitario para diagnóstico in vitro. Importación y distribución de equipos estériles de infusión y jeringas. Diseño, desarrollo, fabricación, asistencia técnica y comercialización de productos sanitarios para diagnóstico in vitro.*

*Conception, développement, fabrication et commercialisation de dispositifs médicaux de diagnostic in vitro. Importation et distribution du ensemble de perfusion et seringues stérile. Conception, développement, fabrication, assistance technique et commercialisation de dispositifs médicaux de diagnostic in vitro.*

*Design, desenvolvimento, fabricação e comercialização de dispositivos médicos para diagnóstico in vitro. Importação e distribuição de conjunto estéril de infusão e seringa. Design, desenvolvimento, fabricação, assistência técnica e comercialização de dispositivos médicos para diagnóstico in vitro.*

*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**

<b>DATES:</b>	<b>FIRST CERTIFICATION</b> <b>PRIMERA CERTIFICACIÓN</b>	<b>CURRENT ISSUE</b> <b>EMISION ACTUAL</b>	<b>EXPIRY</b> <b>VÁLIDO HASTA</b>
	2010-06-04	2022-09-01	2025-06-03

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



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Organismo di Certificazione Federato CISQ  
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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.



SGQ N° 005 A

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 auditorias anuales y a la recertificación  
completa del Sistema de Gestión con una periodicidad trienal

인정번호(No.) : KCL-DBAA-15476

## 체외진단의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업소명/허가번호 (Company name of Applicant / License No.)

주식회사 에이디메디칼/체외 제 4736 호  
ADMEDICAL Co., Ltd.



■ 업소 소재지 (Company address of Applicant)

경기도 하남시 조정대로 150 , 아이테크 그린존 825호  
#G-825, ITECO, 150, Jojeongdae-ro, Hanam-Si, Gyeonggi-do, Republic of Korea

■ 제조소명 (Name of Manufacturer)

제 조 자 : Linear Chemicals SLU

■ 제조소 소재지 (Address of Manufacturer)

제 조 자 : 본사, 공장 Joaquim Costa, 18, 2 planta, 08390 Montgat, SPAIN

■ 품목군 (Category)

붙임참조 ( See attached list)

체외진단의료기기 제조 및 품질관리기준에 적합함을 인정합니다.

(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of In-Vitro Diagnostic Devices for the product group listed above)

발행일자(Date of Issue) : 2022. 10. 07

유효기간(Date of Expiration) : 2025. 10. 06



(재) 한국건설생활환경시험연구원

Korea Conformity Laboratories

