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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATE N. **0462.2020**  
CERTIFICADO N.

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

**HEALTHSENS, S.L.**

C/COLEGIO SANTO DOMINGO DE GUZMÁN BAJO - 33011 OVIEDO (ASTURIAS) SPAIN

OPERATIVE UNITS / *INSTALACIÓN DE*

C/COLEGIO SANTO DOMINGO DE GUZMÁN BAJO - 33011 OVIEDO (ASTURIAS) SPAIN

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

**ISO 13485:2016**

FOR THE FOLLOWING ACTIVITIES / *PARA LAS SIGUIENTES ACTIVIDADES*

Investigación, diseño y fabricación de dispositivos médicos para diagnóstico in vitro (IVD)  
Research, design and manufacture of medical devices for in vitro diagnostic (IVD)

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*

|        |                              |                       |                     |
|--------|------------------------------|-----------------------|---------------------|
| DATES: | FIRST CERTIFICATION          | CURRENT ISSUE         | EXPIRY              |
|        | <i>PRIMERA CERTIFICACIÓN</i> | <i>EMISION ACTUAL</i> | <i>VÁLIDO HASTA</i> |
|        | 2020-03-31                   | 2022-01-19            | 2023-03-30          |

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Management Systems Division - Flavio Ormago



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



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.