



Certificado de Sistema de Gestión de la Calidad de Productos Sanitarios

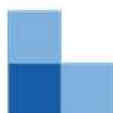


GS-0001/2019

Anexo al Certificado

Alcance: La prestación de servicios de soporte: instalación, puesta en marcha y mantenimiento, de productos sanitarios activos no implantables para los subgrupos y las categorías siguientes: Productos para la circulación extra corporal, infusión y hemoféresis; Productos de respiración, incluyendo anestesia por inhalación; Productos para la estimulación o la inhibición; Productos quirúrgicos activos; Productos oftalmológicos activos; Productos dentales activos; Productos activos para la desinfección y la esterilización; Productos de rehabilitación activos; Productos activos para la colocación y el transporte de los pacientes; Software; Productos para imagen que utilizan radiaciones ionizantes y no ionizantes; Productos de monitorización de parámetros fisiológicos vitales y no vitales; Productos para terapia de radiación y termoterapia que utilizan radiaciones no ionizantes; Productos para la hipotermia y la hipertermia; Productos sanitarios activos (no implantables) para soporte vital, incluyendo incubadoras y cunas térmicas. La importación y distribución de productos sanitarios electromédicos/mecánicos y Productos sanitarios para diagnóstico in vitro: analizadores de gases, bioquímica,

Fecha de primera emisión: 2019-02-02
Fecha de última emisión: 2022-02-02
Fecha de expiración: 2025-02-02



Rafael GARCÍA MEIRO
Director General



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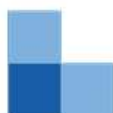


GS-0001/2019

Anexo al Certificado

Alcance: microbiología, tiempo de coagulación y contadores de hematología.

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Rafael GARCÍA MEIRO
Director General





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR has issued an IQNet recognized certificate that the organization:

INSTRUMENTACIÓN Y COMPONENTES, S.A.

**PLATAFORMA LOGÍSTICA PLA-ZA, CL ALAÚN, 8.
50197 - ZARAGOZA**

has implemented and maintains a

Medical devices – Quality Management Systems

for the following scope:

SPECIFIED IN ANNEX TO THE CERTIFICATE

which fulfills the requirements of the following standard

ISO 13485:2016

First issued on: 2019-02-02 Last issued: 2022-02-02 Validity date: 2025-02-02

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ES-GS-0001/2019



Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

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IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNet Certificate Number ES-GS-0001/2019 INSTRUMENTACIÓN Y COMPONENTES, S.A.

Activities within the scope of IQNet Certificate INSTRUMENTACIÓN Y COMPONENTES, S.A. Number ES-GS-0001/2019 include the following:

Support services: installation, commissioning and maintenance of active non-implantable medical devices for the following subgroups and categories: heart-lung bypass machines, infusion and hemophoresis pumps; breathing apparatus, including inhalation anesthesia; machines for stimulation and inhibition; active surgical devices; active ophthalmological devices; active dental devices; active sterilization and disinfection devices; active rehabilitation devices; active devices for the transportation and placement of patients; Software; medical imaging devices that use both ionizing radiation and non-ionizing radiation; devices for the monitoring of vital and non-vital physiological parameters; devices for radiation therapy and thermotherapy that use non-ionizing radiation; devices for hypothermia and hyperthermia; active medical devices (non-implantable) for life support, including incubators and infant warmers.

Import and distribution services for electromedical/mechanical devices and medical devices for in-vitro diagnostic: gas analyzers, biochemistry, microbiology, clotting time, and hematology counters.

First issued on: **2019-02-02** Last issued: **2022-02-02** Validity date: **2025-02-02**

This annex is only valid in connection with the above-mentioned certificate.



Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

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Oy Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway
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IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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