



Certificado de Registro de Empresa Conforme a las exigencias de la norma **INTE/ISO 45001:2018**

**Sistemas de Gestión de la Seguridad y Salud en el Trabajo.
Requisitos con Orientación para su Uso.**

La Asociación Instituto de Normas Técnicas de Costa Rica, INTECO, ubicada en San José, Costa Rica, certifica que la organización:

National Institute of Standardization Association of Costa Rica, INTECO – San José, Costa Rica, certifies that the organization:



HOLOGIC SURGICAL PRODUCTS S.R.L

Cumple con los requisitos para el siguiente alcance:

Manufactura y ensamblaje de dispositivos médicos y la gestión de permisos legales y otros requisitos regulatorios, tanto para la manufactura de dispositivos como para la importación de equipos médicos. Servicios administrativos y de soporte al negocio, soporte técnico y reparación de equipos y maquinaria para la producción de instrumentos y dispositivos médicos. Laboratorios de reclamos de clientes y de aseguramiento de calidad, así como la descontaminación, investigación y análisis de equipos y material biomédico de reclamos, el cual puede ser usado o no; y la disposición de residuos peligrosos que eventualmente pueden ser generados por el proceso.

Manufacturing and assembly of medical devices and the management of legal permits and other regulatory requirements for, both the manufacture of devices and the importation of medical equipment. Administrative and business support services, technical support and repair of equipment and machinery for the production of medical instruments and devices. Customer complaints and quality assurance laboratories, as well as decontamination, research and analysis of equipment and biomedical material for complaints, which may or may not be used; and the disposal of hazardous waste that may eventually be generated by the process.

Que opera en las instalaciones ubicadas en:
which is carried out in

562 Parkway, Av 0, Coyoil Free Zone, Alajuela, Costa Rica

Director Ejecutivo

Fecha de emisión: 2018/03/06

Fecha de Renovación: 2023/07/03

Fecha de expiración: 2026/11/06

El presente certificado es válido exclusivamente para el proceso descrito, no tiene validez sin su correspondiente alcance de la certificación, donde se indica el servicio, las especificaciones y los documentos normativos aplicables, así como número de registro. En caso de duda siempre prevalecerá el alcance en español. | This certificate is valid only for the process described, is not valid without a corresponding scope of certification, indicating the services, specifications and normative documents, and registration number. In case of doubt the spanish written scope will prevail over the english written scope. | FS-MC-37 Versión #2. Revisión #1



Certificate

INTECO has issued an IQNET recognized certificate that the organization:

HOLOGIC SURGICAL PRODUCTS S.R.L.

Alajuela, Costa Rica.

has implemented and maintains a

Safety and health management systems. Requirements.

for the following scope:

Manufacturing and assembly of medical devices and the management of legal permits and other regulatory requirements for, both the manufacture of devices and the importation of medical equipment. Administrative and business support services, technical support and repair of equipment and machinery for the production of medical instruments and devices. Customer complaints and quality assurance laboratories, as well as decontamination, research and analysis of equipment and biomedical material for complaints, which may or may not be used; and the disposal of hazardous waste that may eventually be generated by the process.

which fulfils the requirements of the following standard INTE/ISO 45001:2018:

INTE/ISO 45001:2018

Issued on: 03/07/2023

First issued on: 06/03/2018

Expires on: 06/11/2026

Registration Number: CR-SST-006/2022



Alex Stoichitoiu
President of IQNet

Mauricio Céspedes Mirabelli
Executive Director



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

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