





## **Certificate**

No. Q8 038783 0014 Rev. 00

Holder of Certificate: SEI MEDICAL S.A. DE C.V.

Roberto Fierro #6420 & Francisco Sarabia Parque Industrial Aeropuerto 32695 Ciudad Juárez, Chihuahua

**MEXICO** 

**Certification Mark:** 



**Scope of Certificate:** 

The provision of contract design and development services for non-active medical devices / non-active implants; The provision of contract manufacturer for assembly, packaging and shipping of Non-active Medical Products including: cytology brushes, diagnosis catheters, introducers, urology catheters, breast feeding hygiene kits, endovascular grafts, enteral feeding sets, air filters, ostomy belts, tube fasteners, obstetrics/gynecology suction and irrigation tubes and medical plastic molding.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: <a href="https://www.tuvsud.com/ps-cert?q=cert:Q8 038783 0014 Rev. 00">www.tuvsud.com/ps-cert?q=cert:Q8 038783 0014 Rev. 00</a>

**Report No.:** 72193577

 Valid from:
 2024-05-03

 Valid until:
 2027-05-02

Date, 2024-05-02

Christoph Dicks

Head of Certification/Notified Body



**Product Service** 

## **Certificate**

No. Q8 038783 0014 Rev. 00

ISO 13485:2016 **Applied Standard(s):** 

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): **SEISA MEDICAL INC.** 

9005 Montana, El Paso TX 79925, USA

Receiving and Shipping.

SEI MEDICAL S.A. DE C.V.

Roberto Fierro #6420 & Francisco Sarabia, Parque Industrial Aeropuerto, 32695 Ciudad Juárez, Chihuahua, MEXICO

Contract Manufacturing for Assembly and Packaging.

Medical Plastic Molding.

./.