



Certificate

No. Q5 038783 0013 Rev. 00

Holder of Certificate: **SEI MEDICAL S.A. DE C.V.**
(SEISA MEDICAL INC.)
Roberto Fierro #6420 & Francisco Sarabia
Parque Industrial Aeropuerto
32695 Ciudad Juárez, Chihuahua
MEXICO

Certification Mark:



Scope of Certificate: **Design and Development, 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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 038783 0013 Rev. 00

Report No.: 72163697

Valid from: 2021-05-03
Valid until: 2024-05-02

Date, 2021-05-03



Christoph Dicks
Head of Certification/Notified Body



Product Service

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): SEISA MEDICAL INC.
9005 Montana, El Paso TX 79925, USA

Receiving and Shipping.

SEI MEDICAL S.A. DE C.V. (SEISA MEDICAL INC.)
Roberto Fierro #6420 & Francisco Sarabia, Parque Industrial
Aeropuerto, 32695 Ciudad Juárez, Chihuahua, MEXICO

Design and Development.

Contract Manufacturing for Assembly and Packaging.

Medical Plastic Molding.

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