

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1789390-1
Certificate Holder: DESARROLLO E INVESTIGACION
MEDICA ARAGONESA, S.L.
Polígono Industrial Mediavega, parcela 2.8
50300 Calatayud - Zaragoza
Spain


Scope: Design and development, manufacture and distribution of sterile devices for reconstruction, support and reinforcement of soft tissues, sterile single use transobturator passers, sterile single use retropubic passers with needles and handles, sterile single use anchoring handles.
Manufacture and distribution of components for medical industry using CNC technology.
Manufacture and distribution of components for medical industry using plastic injection technology.
Assembling and packaging of components for medical industry under clean-room conditions.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92782621-40
Effective date: 2025-01-02
Expiry date: 2026-08-29
Issue date: 2025-01-02
Replaces certificate SX 1789390-1 issued 2024-07-31

This certificate can be validated on <https://www.certipedia.com>


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