



CERTIFICATE N° 128-02-00-DM

(in compliance with Annex II of the Directive 93/42/EEC)

ITALCERT S.r.l.

certifies that the

Full Quality Assurance System
applied for the design, manufacture and final inspection of Medical Devices

by the Manufacturer

LSM-MED S.r.l.

Strada Borrana, 38 - 47899 SERRAVALLE - REPUBBLICA SAN MARINO

in the headquarters located in

Strada Borrana, 38 - 47899 SERRAVALLE - REPUBBLICA SAN MARINO

complies with the requirements stated in

Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the Medical Devices reported in Annex 1 of this Certificate

A handwritten signature in blue ink, appearing to read 'Roberto Cusolito'.

Dr. Ing. Roberto Cusolito
MANAGING DIRECTOR

First Issue Date
2018-11-21

Renewal Date
2020-03-23

Expire Date
2024-05-26

This certificate must be published only in integral form and accompanied by its Annex 1
This certificate is the English translation of the certificate n°128-02-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

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Annex 1 to Certificate n° 128-02-00-DM

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Implantable medical devices for osteosynthesis and traumathology (*class IIb*)

Ligament staples
Osteotomy staples
Small-fragments staples
Osteosynthesis nails
Kirschner and other wires
Fiches for external fixators and Epibloc.1 system
Plates
Double threaded screws
Self-breaking screws
Orthopaedic screws and washers
Interference screws
Calcaneus-stop screws
Shape memory staples
Cerclage
PEEK plates for osteosynthesis of humerus
PEEK plates for osteosynthesis of radius
Humeral nail in titanium alloy and PEEK
Diaphyseal femoral plug not resorbable FEM-LOCK

Surgical instruments (*class IIa*)

Reamers with coupling for active device
Screwdrivers with coupling for active device
Guide wires with coupling for active device
Acetabular reamers with coupling for active device
Drill bits and burrs with coupling for active device
Handles and connections with coupling for active device
Taps with coupling for active device
Rasps with coupling for active device
Single use instruments for minimally-invasive surgery

Milan, 2020-03-23



Dr. Ing. Roberto Cusolito
MANAGING DIRECTOR