Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

**No. G2 063838 0015 Rev. 02**

**Manufacturer:** **Medax S.r.l. Unipersonale**
Via R. Piva, 1/A
46025 Poggio Rusco (MN)
ITALY

**Facility(ies):** Medax S.r.l. Unipersonale
Via Sandro Pertini, 4, 41039 S. Possidonio (MO), ITALY

**Product Category(ies):** **Reusable biopsy guns. Veress needles, thoracentesis and paracentesis kits. Vertebroplasty needles. Bone marrow aspiration and biopsy needles. Soft tissue biopsy needles. Punch needles for skin biopsy. Intraosseous infusion needles. Local anesthesia needles.**
**Device for pre-operative localisation of non-palpable lesions of the breast.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** ITA1321318C

**Valid from:** 2020-02-05
**Valid until:** 2024-05-26

Digitally signed by Rotari Vladimir
Date: 2021.09.20 21:16:28 EEST
Reason: MoldSign Signature
Location: Moldova

**Date,** 2020-01-29

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17