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: 2022.01.13 21:27:00 EET
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