ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 04 63838 015

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,
alcoholisation needles, Verres needles,
thoracentesis and paracentesis kits,
vertebroplasty needles and kits.
Bone marrow and aspiration biopsy needles,
Soft tissues biopsy needles.
Punch needles for skin biopsy.
Devices 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.

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Valid from: 2015-06-01
Valid until: 2020-02-04

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Date, 2015-06-03

Hans-Heiner Junker

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

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