



Product Service

# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 10 04 48288 017

**Manufacturer:** ab medica s.p.a.  
Via Nerviano 31  
20020 Lainate (MI)  
ITALY

**Facility(ies):** ab medica s.p.a.  
Via Nerviano 31, 20020 Lainate (MI), ITALY

**Product Category(ies):** Centimetre needle for fiducial implant

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 products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

**Report No.:** ITA 201646

**Valid until:** 2012-11-12



**Date,** 2010-06-30

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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Product Service

# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 09 09 48288 016

<b>Manufacturer:</b>	<b>ab medica s.p.a.</b> Via Nerviano 31 20020 Lainate (MI) ITALY
<b>Facility(ies):</b>	ab medica s.p.a. Via Nerviano 31, 20020 Lainate (MI), ITALY
<b>Product Category(ies):</b>	<b>Class IIa medical devices for preparation of vascular catheterization access:</b> <b>Bowls / trays; contrast lines; contrast syringes; machine covering caps; disposable scalpels; drapes (all kind); extension lines; femoral guidewires; femoral needles; forceps (to fix drapes); gauzes / swabs; gowns; infusion lines; infusion needles; stopcocks and manifolds; examination gloves; surgical gloves; syringes (without needles); Clamps; Angiographic Guidewires; Pigtail catheters; Vascular dilators; Laparotomy sponges, x-ray detectable; Drainage bags; Monitoring lines for pressure measurement; Flush devices; Adhesive strips. Kits for preparation of vascular catheterization access composed of the above mentioned medical devices.</b> <b>Single-use bladeless trocar needle for abdominal surgery.</b> <b>Laparoscopy set for irrigation and suction</b>

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 products / product categories according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

Report No.: ITA 196506

Valid until: 2012-11-12

Date, 2009-11-07

Hans-Heiner Junker



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# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2S 08 09 48288 014

**Manufacturer:** **ab medica s.p.a.**  
Via Nerviano 31  
20020 Lainate (MI)  
ITALY

**Facility(ies):** ab medica s.p.a.  
Via Nerviano 31, 20020 Lainate (MI), ITALY

**Product Category(ies):** **Class I sterile medical devices for preparation of vascular catheterization access for preparation of vascular catheterization access: Bowls/ trays; machine covering caps; drapes (all kind); forceps (to fix drapes); gauzes/ swabs; gowns; examination gloves; syringes without needles; Clamps; Drainage bags; Flush devices; Adhesive strips. Kits for preparation of vascular catheterization access composed of the above mentioned medical devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** ITA 187151

**Valid until:** 2013-10-21

Hans-Heiner Junker

**Date,** 2008-10-22



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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