



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 09 58603 048

Manufacturer: aap Biomaterials GmbH

Lagerstrasse 11-15
64807 Dieburg
GERMANY

Facility(ies):

aap Biomaterials GmbH
Lagerstrasse 11-15, 64807 Dieburg, GERMANY

aap Biomaterials GmbH
Nordring 29, 64807 Dieburg, GERMANY

**Product
Category(ies):**

Mixing and delivery devices for bone cements
and sterile accessories (class IIa)
bone substitute materials (class III)
and bone cements (class IIb + class III)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713061786

Valid from: 2015-10-24
Valid until: 2020-10-23

Date, 2015-09-29

Hans-Heiner Junker



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

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EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC,
Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

PAJUNK GmbH Medizintechnologie

Karl-Hall-Straße 1, 78187 Geisingen, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 51268-Z2-00, the decision dated 2015-03-20 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 2010-03-22

Date of the last recertification: 2015-03-22

This certificate is valid until: 2020-03-21

Certificate registration no. 51268-16-01

DEKRA Certification GmbH
Stuttgart, 2015-03-20

Notified Body ID-number: 0124



Mannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-295:10.02

Use of equipment on conditions as set out in the Certification Agreement may render this certificate invalid

Annex to the EC Certificate 51268-16-01 dated 2015-03-20

Revision status: 0

Date: 2015-03-22

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Devices/device categories included in the certificate

Class II a (non-active):

Cannulas, special cannulas and kits (treatment units) for peripheral regional anesthesia;
Stimulation cannulas, special cannulas and kits for peripheral regional anesthesia with
position verification via electric impulse

Single components (Split cannula, permanent cannula, introducer- and initial puncture
cannulas, stylets, obturator needles, injection syringes, injection tubes, adapter, stimulation
adapter, injection Y-tube, filter, injection cannulas, scalpels, extracorporeal fixations and kits
for

- a) regional anesthesia with optional positional verification via electric impulse
- b) common surgical supply

Cannulas, Special cannulas, treatment units, systems for puncture, aspiration and section for
histology (biopsy) of soft tissue and bone / bone marrow

Cannula for intravenous and intra-arterial (vascular) puncturing

Cannula for endogenous therapy

Dilators, obturators, balloons for dilation, balloons and trocars, trocar sleeves, valves for
fixation for preparation of surgical and minimal-invasive interventions in the field of urology,
gynecology, laparoscopy (hysteroscopy, arthroscopy), histology (biopsy)

Valves, modular instruments (handles, tubes, insert), endoscopes and optics for surgical and
minimal-invasive interventions in the field of urology, gynecology, laparoscopy (hysteroscopy,
arthroscopy), histology (biopsy)

Y-tubes and devices as well as accessories (three-way-stopcock, connection cable)

Switchbox for ECG-monitoring

Transjugular intrahepatic portosystemic shunt

Bolus cannulas, two-way-stopcock, perfusion syringe, sterilin bag within the scope of
longterm analgesia

Cannulas, three-way-stopcock, surgical bag, catheter for general surgery

Cannulas, special cannulas and treatment units for common hospital supply for use
according to physicians indication

Tube, cannulas, syringe and adapter for aerosole local anesthesia of the respiratory system/
the trachea

Cannulas for positioning/ implantation of radioisotopic seeds within the scope of the oncology

Cannulas, special cannulas, treatment units, catheters and forceps for puncture, aspiration,
section and injection of contrast medium, for example for cholangiography (X-ray of the
biliary tract with contrast medium), for mammography and galactography, PTC, not
contacting CSF/ CNS

Cannula for surgical therapy of VUR (VESICO URETERAL REFLUX)

(orthopedic) instrument for creation of cavum

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