

# CERTIFICATE



## EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH hereby certifies that the company

### **PAJUNK GmbH Medizintechnologie**

Karl-Hall-Straße 1, 78187 Geisingen, Germany

**Scope of certification:**

Development, manufacturing, contract manufacturing and distribution of sterile and non-sterile, active and non-active, disposable and reusable medical devices  
(see annex)

**Certified location:**

Karl-Hall-Straße 1, 78187 Geisingen, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51268-Z2-00.

This certificate is valid from 2015-03-22 to 2018-03-21

Certificate registration no.: 51268-11-00  
Duplicate



DEKRA Certification GmbH  
Stuttgart, 2015-03-20



Lack of fulfillment on conditions as set out in the Certification Agreement may render this certificate invalid

# Annex to the Certificate 51268-11-00 dated 2015-03-20

Revision status: 0

Date: 2015-03-22

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## Devices/device categories included in the certificate

### Extended scope

Cannulas, needles, special cannulas, coated and non-coated cannulas, cannulas enhanced for ultrasonic imaging, stimulation cannulas, thermolesion cannulas, multi-part cannulas, introducer cannulas, catheter, special catheter, coiled catheter, stimulation catheter (epidural and peripheral), stimulators, kits and accessories for puncturing, injection, aspiration, biopsy and infusion in Anaesthesia, Analgesia and radiology for cholangiography, angiography, gastroenterology, brachytherapy, TIPS, GLOA, arthroscopy, mammography, galactography

Dental Cartridge syringes, dental cannulas and adapters, ampoule and cartridge carriers, dental needles, injectors, intraligamentary syringes

Laparoscopic instruments, balloons for dilation and fixation, diagnostic and interventional balloon systems and trocar systems, insufflation cannulas, modular monopolar (unipolar) and bipolar HF-electrodes, modular handle instruments, modular suction-irrigation-systems with optional HF connector for surgery and minimal invasive surgery

Cannulas, systems and sets for biopsy and anaesthesia, cementoplasty (e.g. vertebroplasty, kyphoplasty, sacroplasty and skyphoplasty) ECG-monitoring systems, optical endoscopes, endoscopic instruments and accessories

Ambulatory infusion pumps and InfiltraLong Kit with ambulatory infusion pump intended for regional anaesthesia and analgesia / wound infiltration.