



Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Vorsetzen 35 – 20459 Hamburg – Germany**

herewith confirms that the company

**Garantol Products-Santec Medicalprodukte GmbH
Carl-Benz-Straße 17a – 48268 Greven-Reckenfeld
Germany**

has introduced and applies a Quality Management System in the area of

**Design, manufacture and final inspection of
centralvenous and arterial catheters incl. multilumen catheters and
accessories, introducersets, infusionsystems and accessories,
guide wires, catheter and catheter sets for dialysis
Packaging and packing of medical devices for single use**

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2003 + AC:2007

The certification assumes that the company is applying and maintaining its
Quality Management System according to the above given standard. The license of
certification is subject to surveillance by MEDCERT.

This certificate is valid until: 09 November 2012
Hamburg, 28 November 2008

Process No.: QS - 0543
Certificate No.: 0543GB431081128



MEDCERT Certification Body
(Dr. Andreas Schich)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.99.02-46



EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Vorsetzen 35 – 20459 Hamburg – Germany

herewith confirms that the company

Garantol Products-Santec Medicalprodukte GmbH
Carl-Benz-Straße 17a – 48268 Greven-Reckenfeld
Germany

has introduced and applies a Quality Management System
for the products / product category

Centralvenous and arterial catheters incl. multilumen catheters
including accessories, introducers sets,
infusionsystems and accessories, guide wires,
catheters and catheter sets for dialysis

An Audit demonstrated compliance of the Quality Management System with

Annex II

of the **Council Directive 93/42/EEC concerning Medical Devices.**

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given annex. The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 09 November 2012

Hamburg, 28 November 2008

Process No.: QS - 0543

Certificate No.: 0543GB410081128

MEDCERT Identification No.: 0482


MEDCERT Certification Body
(Dr. Andreas Schich)



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Zentralstelle der Länder
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bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.94.13