



## 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

**Microtek Medical B.V.**  
Hekkehorst 24 – 7207 BN Zutphen – Netherlands  
for the facility

**Microtek Medical Malta Limited**  
F 20, Sorbonne Centre – Mosta Technopark  
Mosta MST 02 – Malta

has introduced and applies a Quality Management System  
**for the aspects of manufacture concerned with  
securing and maintaining sterile conditions**  
for the products / product categories

**Medical camera drapes, copolymere gloves,  
thorax drainage systems**

An Audit demonstrated compliance of the Quality Management System with

### Annex V

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: 22 April 2011**  
Hamburg, 17 November 2008

Process No.: QS – 6067B  
Certificate No.: 6067GB415081117B  
MEDCERT Identification No.: 0482

MEDCERT Certification Body  
(Dr. Andreas Schich)



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-983.94.13



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

### **Catheter introducer, wound drains**

An Audit demonstrated compliance of the Quality Management System with

### **Annex V**

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

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