

# **MED/CERT**

## **Certificate**

### **The Certification Body**

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**MHM Harzbecher Medizintechnik GmbH**  
**Erthalstraße 12 – 63739 Aschaffenburg**  
**Germany**

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

**Design, manufacture and final inspection of  
sets for cardiology, radiology, anaesthesia, gastroenterology and  
urology as well as components for sets for cardiology, radiology,  
anaesthesia, gastroenterology and urology, drapes, covers,  
protective films, pressure transducer and accessories**

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: 20 May 2013**

Hamburg, 20 September 2010

Process No.: QS - 1265

Certificate No.: 1265GB431100920

MS



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  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**MHM Harzbecher Medizintechnik GmbH  
Erthalstraße 12 – 63739 Aschaffenburg  
Germany**

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

**Sets for cardiology, radiology, anaesthesia and urology  
as well as components for sets for  
cardiology, radiology, anaesthesia and urology,  
protective films, pressure transducer and accessories**

An Audit demonstrated compliance of the Quality Management System with

**Annex II**  
excluding section (4)

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: 20 May 2013**  
Hamburg, 20 September 2010

Process No.: QS - 1265  
Certificate No.: 1265GB410100920  
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



## 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

**MHM Harzbecher Medizintechnik GmbH**  
**Erthalstraße 12 – 63739 Aschaffenburg**  
**Germany**

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

### **Drapes, covers and protective films**

An Audit demonstrated compliance of the Quality Management System with

### **Annex V**

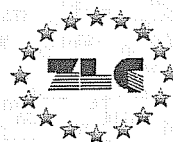
of the **Council Directive 93/42/EEC concerning Medical Devices.**

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: 20 May 2013**  
Hamburg, 20 May 2008

Process No.: QS - 1265  
Certificate No.: 1265GB415080520  
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