

# Certificate

**mdc medical device certification GmbH**

certifies that



**Kastner-Praxisbedarf GmbH Medizintechnik  
Berliner Ring 40, 76437 Rastatt  
Germany**

for the scope

**development, manufacture and distribution of:**

- ✔ **UV-blood radiation devices (HOT) and accessories for HOT / UVB**
- ✔ **Ozone therapy devices**
- ✔ **Sterile vacuum bottles (250 cc and 500 cc) for autohaemotherapy**
- ✔ **Sterile Sodium Citrate (Natrium Citrate) for autohaemotherapy**
- ✔ **Colon speculum for colon-hydro-therapy**

**service and maintenance for ozone and blood-radiation devices (HOT/UVB)  
Trading of medical equipment and disposables**

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

**EN ISO 13485**

**Medical devices – Quality management systems –  
Requirements for regulatory purposes**

(EN ISO 13485:2003 + AC:2007)

Valid from	2009-09-03
Valid until	2014-09-03
Registration no.	0368.48.11/0
Report no.	E 0368.48 / 2009-08-21
Stuttgart	2009-08-21

Head of Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-976.00.03-46

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that



**Kastner-Praxisbedarf GmbH Medizintechnik**  
**Berliner Ring 40, 76437 Rastatt**  
**Germany**

for the scope

- **Ozone therapy devices**
- **UV-blood radiation devices (HOT) and accessories for HOT**
- **Accessories for ultraviolet blood radiation (UVB and UVE)**
- **Colon speculum for colon-hydro-therapy**
- **Sterile Sodium Citrate (Natrium Citrate) for autohaemotherapy**
- **Sterile vacuum bottles (250 cc and 500 cc) for autohaemotherapy**

has introduced and applies a

## Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

## Annex II – Section 3 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2009-09-03
Valid until	2014-09-03
Registration no.	0368.01.21/0
Report no.	E 0368.01 / 2009-08-21
Stuttgart	2009-08-21

Head of Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-976.94.05