



# EC - CERTIFICATE

## DQS GmbH

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company



## Helm Medical GmbH

Nordkanalstraße 28  
20097 Hamburg  
Germany

has implemented and maintains a

### Quality Management System.

An audit, documented in a report, performed by DQS  
has verified that this quality management system  
fulfills the requirements of

### Annex V of Directive 93/42/EEC

with respect to the following medical devices:

Medical products for single use according to annex

As set out in section 4, Annex V, of the said directive, the manufacturer of these devices is subject to surveillance.  
The CE-mark with the number of the notified body may be used on the devices listed in the certificate.

**CE 0297**

This certificate is valid until 2013-07-12

Certificate Registration No. 416447 MR5

Frankfurt am Main 2008-07-13

Ass. iur. M. Drechsel

Dipl.-Ing. S. Heinloth

MANAGING DIRECTORS

D-60433 Frankfurt am Main, August-Schanz-Straße 21

EC code number of DQS as notified body: 0297



**Annex to Certificate Registration No.: 416447 MR5  
(Edition 2008-07-13)**

**Helm Medical GmbH**

Nordkanalstraße 28  
20097 Hamburg  
Germany

**Product categories**

**Products**

gloves

surgical gloves  
Gynaecological gloves

AD-syringes

auto-disable syringes with (fixed) needles

syringes

disposable syringes with and without needles

needles

hypodermic needles

tubes

endotracheal tubes

infusion sets

i. v. infusion sets  
i. v. infusion sets (scalp vein)

devices for blood transfusions

blood transfusion sets

stopcocks

3-way stopcocks (for infusion)

catheter

i.v. catheter (peripheral)  
urinary catheters

obturator

Obturator for i.v. Catheter