



# C E R T I F I C A T E

## **DQS GmbH**

**Deutsche Gesellschaft zur Zertifizierung von Managementsystemen**

hereby certifies that the company



## **Helm Pharmaceuticals GmbH**

Nordkanalstraße 28  
D-20097 Hamburg

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 products:

Medical products for single use according to annex

As set out in section 4, Annex V, of the said directive,  
the manufacture of these devices is subject to surveillance.

This certificate is valid until 2008-11-18

Certificate Registration No.: 066201 MR5

Frankfurt am Main, Berlin 2003-11-19

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MANAGING DIRECTOR

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EC code number of DQS as notified body: 0297



## Annex to Certificate Registration No.: 066201 MR5

### Helm Pharmaceuticals GmbH

Nordkanalstraße 28  
D-20097 Hamburg

<b>Product categories</b>	<b>Products</b>
gloves	surgical gloves
syringes	disposable syringes with and without needles
needles	disposable needles
tubes	endotracheal tubes
infusion sets	i. v. infusion sets i. v. infusion sets (scalp vein)
devices for blood transfusions	blood transfusion sets
stopcocks	disposable stopcocks (for infusion)
catheter	i.v. catheter (peripheral) sterile urinary catheters for intermittent catheterisation

This annex is valid only in connection  
with the above-mentioned certificate.