

# Certificate

## Design Examination

No. CE 90656



Issued to:

**Gambro Kathetertechnik Hechingen**  
**Zweigniederlassung der Gambro**  
**Dialysatoren GmbH**  
**Linsenaecker 1**  
**72379 Hechingen**  
**Germany**

In respect of:

**Dialysis Double Lumen Silicone Catheter with Cuff for long term use (up to one year)**

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to be 'D. Ford', written over a horizontal line.

David Ford, Director, Healthcare and Testing Services

First Issued: 15 Apr 2005

Date: 9 Apr 2010

Expiration Date: 14 Apr 2015

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*Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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## Supplementary Information to CE 90656

Issued to:

**Gambro Kathetertechnik Hechingen Zweigniederlassung der Gambro  
Dialysatoren GmbH  
72379 Hechingen  
Germany**

Product Range	Size Range
GDSC 15F (5mm)	120 – 330mm
GDSK 15F (5mm)	120 – 330mm

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### History of Certificate

Date	Reference Number	Action
15 April 2005	10062953	First issue
29 June 2009	10105765	The correction of company name from 'Gambro Kathetertechnik Hechingen Zweigniederlassung Gambro Dialysatoren GmbH' to 'Gambro Kathetertechnik Hechingen Zweigniederlassung der Gambro Dialysatoren GmbH'
09 April 2010	10115607	Amend scope from Dialysis Catheter Silicone with Cuff, to read Dialysis Double Lumen Silicone Catheter with Cuff for long term use (up to one year). Certificate renewal

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