



## EC Certificate

### Production Quality Assurance System

Directive 90/269/EEC on Medical Devices (MDD), Annex II  
(Directive 90/269/EEC)

No. 02 15 07 81950 000

<b>Manufacturer:</b>	<b>Shanghai XinChang Medical Device Co., Ltd.</b> 46 Fuxi Rd. 25 Lane 1, Nanyang Fudan Garden 20021 Shanghai PEOPLE'S REPUBLIC OF CHINA
<b>EC Representative:</b>	<b>Shanghai International Holding Corp. GmbH (Europe)</b> Helmholtz St. 12271 Berlin GERMANY
<b>Product Category(ies)</b>	<b>Biliary Drainage Catheter</b>

The Certificate Body of TÜV SÜD Product Service GmbH declares that the administrative manufacturer has implemented a quality assurance system for manufacture and final inspection of biliary drainage catheter in accordance with MDD Annex II. The quality assurance system conforms to the requirements of the Directive and is subject to periodic surveillance. The handling of non-conforming devices or withdrawal issues is described in instruction. For more info contact:

<b>Report No.</b>	02102290
<b>Valid from</b>	01/12/2011
<b>Valid until</b>	01/12/2012



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