



**InterCert**  
Zertifizierungsgesellschaft mbH  
Umweltgutachterorganisation

# Certificate

The LGA InterCert GmbH – notified body no. 1275 according to the EC Directive concerning medical devices – herewith confirms that the following company



**Elana BV**  
**Yalelaan 44**  
**3584 CM Utrecht**  
**The Netherlands**

has introduced and applies a

## Quality Management System

for medical devices according to

### DIN EN ISO 13485:2003

Requirements for regulatory purposes

**for the scopes design, manufacturing, distribution and servicing of  
Elana Catheter 2.0 and Elana Rings 2.6 and 2.8**

Proof of fulfillment of the above-mentioned standard has been provided by the certification through LGA InterCert.

This certificate is valid until October 9, 2010  
Registration no.: 1851854-038-000

Audit report no.: 1851854  
of: August 26, 2005

Nuremberg, October 10, 2005

  
Roland Gruber  
Certification Office  
Medical Devices



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
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