

# Certificate

The LGA InterCert Zertifizierungsgesellschaft mbH, a designated registrar for quality management systems, 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

### EN ISO 13485:2003 + AC:2009

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, 2015  
Registration no.: **1901816-042-000**

Audit report no.: 1901816  
of: July 2, 2010

Nuremberg, October 10, 2010

  
\_\_\_\_\_  
Roland Gruber  
Head of Certification Office  
Medical Devices



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-239.10.13**