

# EC Design-Examination Certificate

The LGA InterCert GmbH – **Notified Body 1275** according to the EC Directive concerning medical devices – herewith certifies that the company



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

has drawn up an examination dossier for the product

## **Elana Catheter 2.0**

with the intended purpose to provide an arteriotomy in the wall of an artery.

LGA InterCert GmbH has performed an examination of the design dossier and found that the design of the device conforms to the requirements of

## **Directive 93/42/EEC, Annex II (4).**

This certificate is valid until October 9, 2015  
Registration no.: **1901816-007-002**

EC Design examination report no.: 1901816-2/1<sup>st</sup> Renewal  
of: August 19, 2010

Nuremberg, October 10, 2010<sup>(\*)</sup>

Roland Gruber  
Head of Certification Office  
Medical Devices



(\*) first issue October 10, 2005, Reg. no.: 1851854-007-001