

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Elana B.V.
Yalelaan 44
3584 CM Utrecht
Netherlands

has established and applies a quality management system for medical devices
for the following scope:

**Design, manufacturing, distribution and servicing of
Elana Catheters 2.0 and Elana Rings 2.6 and 2.8**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-10-28
Certificate Registration No.: SX 60104406 0001
An audit was performed. Report No.: 21238999 001
This Certificate is valid until: 2018-10-27

Certification Body



Date 2015-10-28



Dipl.-Ing. D. Meier

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