

EC Certificate

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



Elana

Elana bv
Yalelaan 44
3584 CM Utrecht
The Netherlands

applies a

Full Quality Assurance System

for the design, manufacture and final inspection of the medical devices
as specified in the enclosure

according to

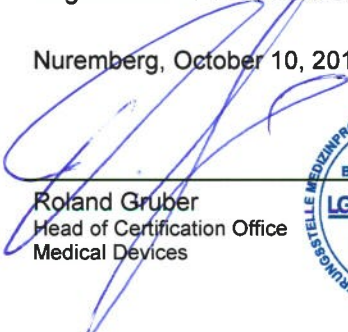
Directive 93/42/EEC, Annex II excluding (4).

In a certification audit carried out by LGA InterCert GmbH, evidence was furnished proving that the quality system of the company fulfills the requirement of the above-mentioned directive.
The surveillance through the LGA InterCert GmbH is effected according to Annex II (5).

This certificate is valid until October 9, 2015
Registration no.: 1901816-006-000

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

Nuremberg, October 10, 2010


Roland Gruber
Head of Certification Office
Medical Devices



It is allowed for the company to sign the products specified in the enclosure with the adjoining sign.

CE 1275

**Enclosure of the Certificate Registration no. 1901816-006-000 of the company
Elana bv, Yalelaan 44, 3584 CM Utrecht, The Netherlands**

Period of Validity October 10, 2010 until October 9, 2015

The above-mentioned certificate refers to the following medical devices:

No.	Product	UMDNS-No.	Class
1.	Elana Rings 2.6 and 2.8	*	III
2.	Elana Catheter 2.0	*	III

*At present no UMDNS number is available.

For the placing on the market of Class III devices covered by this certificate, an EC design-examination certificate according to MDD Annex II (4) is required.

Nuremberg, October 10, 2010


Roland Gruber
Head of Certification Office
Medical Devices

