

# Certificate



TUV Rheinland of North America, Inc., a CMDCAS  
recognized registrar, certifies that

**Elana B.V.  
Yalelaan 44  
3584 CM Utrecht  
Netherlands**

has established and maintained a  
**Quality Management System  
according to  
ISO 13485:2003**

Audit Report No.: 21238999 001  
Certificate Registration No.: 74 500 4746  
Expiry Date: October 27, 2018

for the design, manufacturing, distribution and servicing  
of ELANA Catheters and ELANA Rings  
for neurosurgical bypass techniques



A handwritten signature in blue ink, likely belonging to the Certification Officer.

Certification Officer: Dipl.-Ing. D. Meier

**TUV Rheinland of North America, Inc.  
Newtown, Connecticut**

Effective Date: October 28, 2015  
Issue Date: October 28, 2015