



# Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**APPROVES THE QUALITY SYSTEM APPLIED BY**

## NeoTract, Inc

**4473 Willow Rd.  
Suite 100  
Pleasanton  
CA 94588  
USA**

*to the Product Family*

### Prostatic Retraction Implant

**GMDN Code: 58882**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex  
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.1059</b>
<b>Original Approval:</b>	<b>11 November 2009</b>
<b>Last Amended on:</b>	<b>27 April 2016</b>
<b>Remains valid until:</b>	<b>10 November 2018</b>

**Signed:**

Approved by:  
Kevin D. Mullaney  
Chief Executive Officer - NSAI Inc.

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**  
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**