



# Certificate

## EC design-examination certificate

according to annex II section 4 of the  
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

### BSI Group Deutschland GmbH

Eastgate, Hanauer Landstrasse 115  
60314 Frankfurt am Main  
Germany

in its function as Notified Body (0535), that the manufacturer:



### Ernst Kratz GmbH

### Nadel- und Kanülentechnologie

Landsteiner Str. 2  
63303 Dreieich, Germany

submitted a design dossier concerning the medical device  
**needle suture combination, PDO**  
(products/variants specified in appendix)

The design of the product was assessed and fulfils the  
requirements according to Annex II section 4 of the Medical  
Devices Directive 93/42/EEC. For marketing of these  
products an associated Annex II.3 certificate is mandatory.

The appendix is part of this certificate and contains 1 page.

Report No.: SMO8255845  
**Certificate No.: CE 574593**



First Issue Date:  
August 18, 2010.

With an annual surveillance  
the regular certification cycle would be  
August 18, 2015 until August 17, 2020.  
Due to the closure of Notified Body NB0535  
the certificate is valid until June 30, 2016.

Current Issue Date: February 12, 2016

*E. Schwöder*  
Certification Body

## EC design-examination certificate

according to annex II section 4 of the Medical Devices Directive 93/42/EEC

Certificate No.: CE 574593

Medical devices of the manufacturer:



**Ernst Kratz GmbH**

**Nadel- und Kanülentechnologie**

Landsteiner Str. 2

63303 Dreieich, Germany

Name of product	UMDNS	Class
needle suture combination, PDO	16-584	III

### Needle and Suture combinations from within the following sizes

Description	Dimensions	Ausführung in Schritten von
<i>Suture size</i>	<i>USP 12/0 - USP12</i>	<i>1</i>
<i>Suture lengths</i>	<i>20mm -2000mm</i>	<i>5mm</i>
<i>Needle wire diameter</i>	<i>0,150mm -3,0mm</i>	<i>0,05 mm</i>
<i>Needle lengths</i>	<i>4mm – 200 mm</i>	<i>0,5 mm</i>
needle curvature	N/A	straight, 3/8-curved, 1/2-circle, 5/8-curved
needle body shape	N/A	round body, reverse cutting
needle tips	N/A	Trocar cutting taper lancet blunt spatula micro taper cutting

Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-248.10.04



Frankfurt am Main, February 12, 2016

Certification Body

*E. Schwöder*

