

EC design-examination certificate
according to annex II, section 4 of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

**EUROCAT Institute for
Certification and Testing**

Quarat[®] Center * Wittichstrasse 2
64295 Darmstadt * Germany
Identification No. 0535,
in its function as Notified Body,

that the manufacturer



**Ernst Kratz GmbH
Nadel- und Kanülentechnologie
Landsteiner Str. 2**

63303 Dreieich, Germany
submitted a design dossier
concerning the medical devices
needle suture combination, PGA
(products/variants specified in enclosure)

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

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

The certificate is valid until 17 August 2015.

Report No.: APB10229HU01

Certificate No.: CQ102302-II4

CE 0535



Accredited by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-914.99.04

Darmstadt, 18 August 2010



Certification Body

Enclosure of EC design-examination certificate
 according to annex II, section 4, Medical Devices Directive 93/42/EEC
Certificate No.: CQ102302-II4

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, PGA | 13-908 | 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 |

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