



Certificate

EC-Certificate

(full quality assurance system)

according to annex II (excluding section 4) of
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

concerning the medical device

Resorbable and non-resorbable needle suture combination

(products/variants specified in appendix)

fulfils the requirements according to Annex II (excluding section 4) Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the design, production and final inspection of the specified devices.

For the placing on the market of class III products an additional Annex II section 4 certificate is required.

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

Report No.: SMO8130928

Certificate No.: CE 574591

Current Issue Date: February 12, 2016



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.

E. Schröder

Certification Body



Appendix of EC-Certificate

(full quality assurance system)

according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC

Certificate No.: CE 574591

Medical devices of the manufacturer:



Ernst Kratz GmbH

Nadel- und Kanülentechnologie

Landsteiner Str. 2

63303 Dreieich, Germany

Name of produkt	UMDNS	Class
needle suture combination, PP	13-909	IIb
needle suture combination, Nylon	13-905	IIb
needle suture combination, Polyester	13-906	IIb
needle suture combination, Silk	13-910	IIb
needle suture combination, others	15-255	IIb
needle suture combination, stainless steel	15-971	IIb
needle suture combination, PGA	13-908	III*
needle suture combination, PDO	16-584	III*

* Annex II section 4 certificates exist for both of the class III products.
(PDO = CE 574593; PGA = CE 574594)



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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Frankfurt am Main, February 12, 2016


E. Schöden
 Certification Body