



Certificate

EC-Certificate

(Production quality assurance system)

according to annex V 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

Landsteinerstr. 2
63303 Dreieich
Germany

concerning the medical devices

surgical needles, sterile

UMDNS: 12-754, Class IIa

Ø 0,35mm – 2,2mm; length: 4mm – 140mm

fulfils the requirements according to Annex V of the Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the production and final inspection of the specified devices. For the placing on the market of class III products an Annex III certificate is required.

Report No.: SMO8033971

Certificate No.: CE 574590



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

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Based on periodical surveillance
this certificate is valid until
May 25, 2019.

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Schwödel
Certification Body

