

**EC-Certificate**

(Production quality assurance system)  
according to annex V, section 3  
Medical Devices Directive 93/42/EEC

It is herewith confirmed by the Notified Body  
**EUROCAT Institute for  
Certification and Testing**  
Quarat<sup>®</sup> Center, Wittichstraße 2  
64295 Darmstadt, Germany  
Identification No. 0535

that the manufacturer



**Ernst Kratz GmbH**  
**Nadel- und Kanülentechnologie**  
**Landsteiner Str. 2**  
**63303 Dreieich, Germany**  
concerning the medical device  
**surgical needles, sterile**  
UMDNS: 12-754

fulfills the requirements according to Annex V,  
section 3, Medical Devices Directive 93/42/EEC.  
The manufacturer has established a quality  
assurance system for the production and final  
inspection of specified devices.

Date of initial registration: 26 May 2009

Based on the periodical surveillance the  
certificate is valid until 25 May 2014.

Report No.: BQM10187HU01  
Certificate No.: **CQ102301-V**

**CE 0535**



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

Darmstadt, 18 August 2010

  
  
Certification Body