



# CERTIFICATE

The certification body of Swiss TS Technical Services AG hereby certifies that the company

**Instrumed International GmbH**  
**Unter Buchsteig 3**  
**D-78532 Tuttlingen**

has introduced and applies a management system for

**Development, Manufacturing and Distribution of Surgical Instruments and Implants**

according to:

**ISO 9001:2008      Quality management**  
**ISO 13485:2003    for medical devices**

|                             |            |            |
|-----------------------------|------------|------------|
|                             | ISO 9001   | ISO 13485  |
| Registration number:        | 06-294-027 | 06-294-027 |
| Initial certification date: | 13.02.2006 | 13.02.2006 |
| Valid until:                | 29.10.2012 | 29.10.2012 |

Heinrich A. Bieler

Wallisellen, 10.07.2009  
 The certification body  
 of Swiss TS Technical Services AG  
 A SVTI and TÜV SÜD company



# CE-Certificate

Full quality assurance system

The conformity assessment body for medical devices of Swiss TS Technical Services AG hereby certifies that :

**Instrumed International GmbH**  
**Unter Buchsteig 3**  
**D-78532 Tuttlingen**

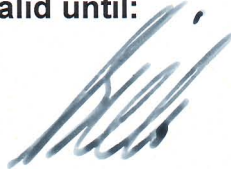
**has introduced and applies a full quality assurance system according to annex II.3 of directive 93/42 EEC**

The full quality assurance system covers design, manufacture and final inspection of the products according to the requirements of annex II.3 of the directive 93/42 EEC. The quality assurance system is regularly controlled by Swiss TS Technical Services AG according to annex II.5.

**for the product categories**

**Surgical Instruments, Endoscopes and Accessories, HF-Instruments and -Electrodes, Rib Retractors, Self-Retaining Retractors, Vascular Clamps, Cannulae, Verres Needles, Trocar-Systems, sterile and non-sterile Orthopedic Implants and Instruments, Bone-Saws, Bone-Drills, Bone-Reamers; refer to annexed product list**

Registration number: 07-297-704  
 First certification: 22.05.2007  
 Valid until: 29.10.2012



Wallisellen, 10.07.2009  
 Notified Body CE 1253 of  
 Swiss TS Technical Services AG  
 Richtstrasse 15  
 CH-8304 Wallisellen  
 Swiss TS, a company of SVTI and TÜV SÜD

**CE1253**



SCESm 013

**Annex**

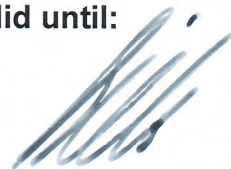
**To CE-Certificate Production Quality assurance**

**Instrumed International GmbH  
 Unter Buchsteig 3  
 D-78532 Tuttlingen**

| Product Categories                                                               | Class | Rule | UMDNS  |
|----------------------------------------------------------------------------------|-------|------|--------|
| Saws, Bone (Sägeblätter)                                                         | Ila   | 6    | 13-449 |
| Burs Orthopedic (Bohrer, orthopädisch)                                           | Ila   | 6    | 17-995 |
| Reamers Orthopedic (Bohrer, orthopädisch)                                        | Ila   | 6    | 13-297 |
| Plates, Bone (Platten, Knochen)                                                  | Ilb   | 8    | 13-050 |
| Wire, Bone (Draht, Knochen)                                                      | Ilb   | 8    | 16-104 |
| Screw, Bone (Schraube, Knochen)                                                  | Ilb   | 8    | 16-101 |
| Nails, Bone (Nagel, Knochen)                                                     | Ilb   | 8    | 16-078 |
| Trocars (Trokare)                                                                | Ila   | 7    | 14-154 |
| Cannulae, other (Kanüle / Saug- Spül)                                            | Ila   | 7    | 15-206 |
| Clamps, other (Klemmen, andere)                                                  | Ila   | 7    | 15-212 |
| Clamps, vascular (Klemmen, Gefäß)                                                | Ila   | 7    | 16-028 |
| Retractors, self-retaining operating (Wundhaken, selbstsperrend)                 | Ila   | 7    | 13-390 |
| Spreaders, rib (Spreizer, Rippen)                                                | Ila   | 7    | 13-709 |
| Electrodes, Electrosurgical, Active (Elektrode, HF-Chirurgie, Aktivelektrode)    | Ilb   | 9    | 16-860 |
| Electrodes, Electrosurgical (Elektrode, HF-Chirurgie)                            | Ilb   | 9    | 15-579 |
| Electrodes, Electrosurgical, Return (Elektrode, HF-Chirurgie, Neutralelektrode)  | Ila   | 7    | 11-500 |
| Needles, Pneumoperitoneal / Verresneedle (Nadel, pneumoperitoneal / Veressnadel) | Ila   | 7    | 12-750 |
| Rigid Endoscopic/Multipurpose (starres Endoskop/Mehrzweck-)                      | Ila   | 7    | 16-831 |
| Laparoscopes (Laparoskop)                                                        | Ila   | 7    | 12-291 |
| Rhinoscopes (Rhinoskop)                                                          | Ila   | 7    | 13-396 |

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