

# DET NORSKE VERITAS

## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 80567-2010-CE-CZS-NA  
This Certificate consists of 3 pages

*This is to certify that the Quality Management System of*

**MEDIN, a.s.**

Vlachovická 619, 592 31, Nové Město na Moravě, Czech Republic

*for design, production and final product inspection/testing of*

**Sterile and Non Sterile Medical Devices**

*has been assessed with respect to*

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*

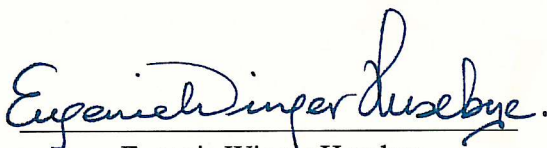
Høvik, 5 August 2010

*This Certificate is valid until:*

14 June 2015

For DET NORSKE VERITAS CERTIFICATION AS  
NORWAY





Eugenie Winger Husebye  
Certification Manager



Notified Body No.:  
0434

Aud Løken Eiklid  
Technical Reviewer

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://www.dnv.com/digitalsignatures) for more info*

**Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.**

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 80567-2010-CE-CZS-NA  
 Rev. No.:  
 Project No.: PRJC-89313-2008-PRC-CZE

### Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

### Certificate history

| Revision | Description  | Issue Date |
|----------|--|------------|
|          | Original certificate, referring to previous certificates No.:<br>2005-OSL-MDD-0212, 2005-OSL-MDD-0213, 2005-OSL-MDD-0214 | 2005-06-14 |
|          | Recertification  | 2010-06-14 |

### Products covered by this Certificate

| Product Description                    | Product   | Class |
|--|---|-------|
| Reusable Surgical Medical Devices      | <ol style="list-style-type: none"> <li>1. Electrodes and forceps for coagulation (intended for connection to active medical devices CHIRATOM 70/ERBE)</li> <li>2. Needles, puncture needles, liposuction cannulas, cannulas suction tubes, suction curettes</li> <li>3. Drills and burrs and other rotary devices for surgery (connecting with active medical devices)</li> <li>4. Instruments for haemorrhoids</li> <li>5. Mesh strengtheners</li> </ol> | IIa   |
| Dental Medical Devices                 | <ol style="list-style-type: none"> <li>1. Dental rotary instruments and rotary instruments sets non sterile</li> <li>2. Dental rotary instruments and rotary instruments sets sterile - Barbed Broach (pulp needles)</li> <li>3. Aids for stomatology (orthodontic and other products)</li> </ol>   |       |
| Non Active Implantable Medical Devices | <ol style="list-style-type: none"> <li>1. Bone screws and washers</li> <li>2. Plates</li> <li>3. Staples</li> <li>4. Pins</li> <li>5. Implants for spine</li> <li>6. Hip implants (Retentive reticle and baskets using for total hip replacements/Acetabular reticle)</li> <li>7. Intramedullary nails</li> </ol>   | IIb   |

The complete list of devices is filed with the Notified Body.



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### Sites covered by this certificate

| Site Name   | Address  |
|-------------|--|
| MEDIN, a.s. | Vlachovická 619,592 31,Nové Město na Moravě,Czech Republic |

### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE