

APPROVAL
EC Directive 93/42/EEC; Annex II without Article 4
Full Quality Assurance System
Medical Devices

Registration No.: OH 69241209 0001

Report No.: 28211417 001

Manufacturer: **MEDIMETÁL Gyógyászati Termékeket
Gyártó és Forgalmazó Kft.**

Berva-völgy hrsz.: 2478
H-3304 Eger
Hungary

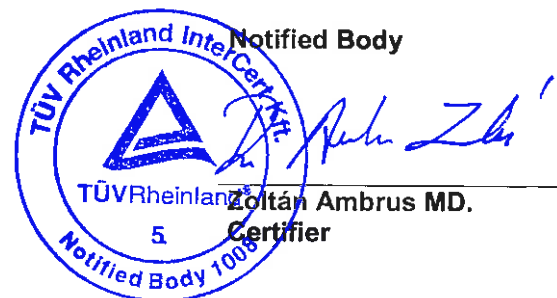
Scope: Design/Development and production of bone surgery implants

Date of expiry: 2016-09-21

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II (without Article 4) of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's Declaration of Conformity.

Budapest, 2011-09-22

Page: 1 / 3



TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

Notified under No. **1008** to the EC Commission.

The CE marking may be used if all relevant and effective EC Directives are complied with.

ATTACHMENT

Registration No.: OH 69241209 0001
Report No.: 28211417 001
Organization: MEDIMETÁL Gyógyászati Termékeket
Gyártó és Forgalmazó Kft.

Berva-völgy hrsz.: 2478
H-3304 Eger
Hungary

Scope: Products:

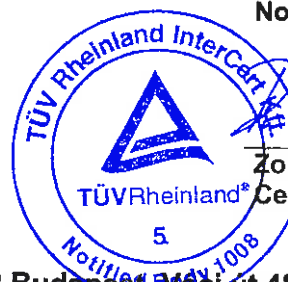
Bone screws

- Cortical bone screw
- Cancellous bone screw
- Femoral neck screw
- Dynamic bone screw
- Locking bone screw
- Special bone screw

Bone plates

- Maxillo facial bone plates
- Spinal plate
- Shoulder plate
- Humeral plate
- Ulna plate
- Hand plate
- Chest plate
- Pelvic plate
- Femoral plate
- Tibial plates
- Foot plate
- Dynamic bone plate

Notified Body



Zoltán Ambrus MD.
Certifier

Page: 2 / 3

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci ut 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, <http://www.tuv.com/hun/>

Notified under No. 1008 to the EC Commission.

The CE marking may be used if all relevant and effective EC Directives are complied with.

ATTACHMENT

Registration No.: OH 69241209 0001
Report No.: 28211417 001
Organization: MEDIMETÁL Gyógyászati Termékeket
Gyártó és Forgalmazó Kft.

Berva-völgy hrsz.: 2478
H-3304 Eger
Hungary

Scope: Products:

Intramedullary nails

- Humerus nails
- Femoral nails
- Tibial nails
- Humerus pin
- Femoral pin
- Tibial pin

Spinal implant system

- Spinal rods
- Monoaxial and polyaxial screws
- Spinal hooks
- Connecting components
- Sacral fixing components

Pin

Bone staple

Wires

Nuts

Washers



Notified Body

Zoltán Ambrus MD.
Zoltán Ambrus MD.
Certifier

Page: 3 / 3

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

Notified under No. 1008 to the EC Commission.

The CE marking may be used if all relevant and effective EC Directives are complied with.