



NOTIFIED BODY No. 1023
Institute for Testing and Certification, Inc., Zlín, Czech Republic

EC CERTIFICATE

No. 07 0566 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIb and IIa, models

Orthopaedic Implants of Class IIb & IIa
(Screws, Plates, Nails, Pins, Wires, Spine Implants, External Fixators)
(For detailed specification refer to Annex; pages 1-6)

manufactured by company

NEWLIFE SURGICALS WORKS

1681/4, Bhagirath Palace,
Chandni Chowk, Delhi - 110006, India

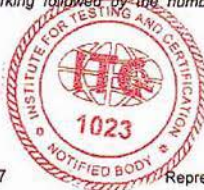
are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600246/2007, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 7th October 2012 at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:

CE 1023

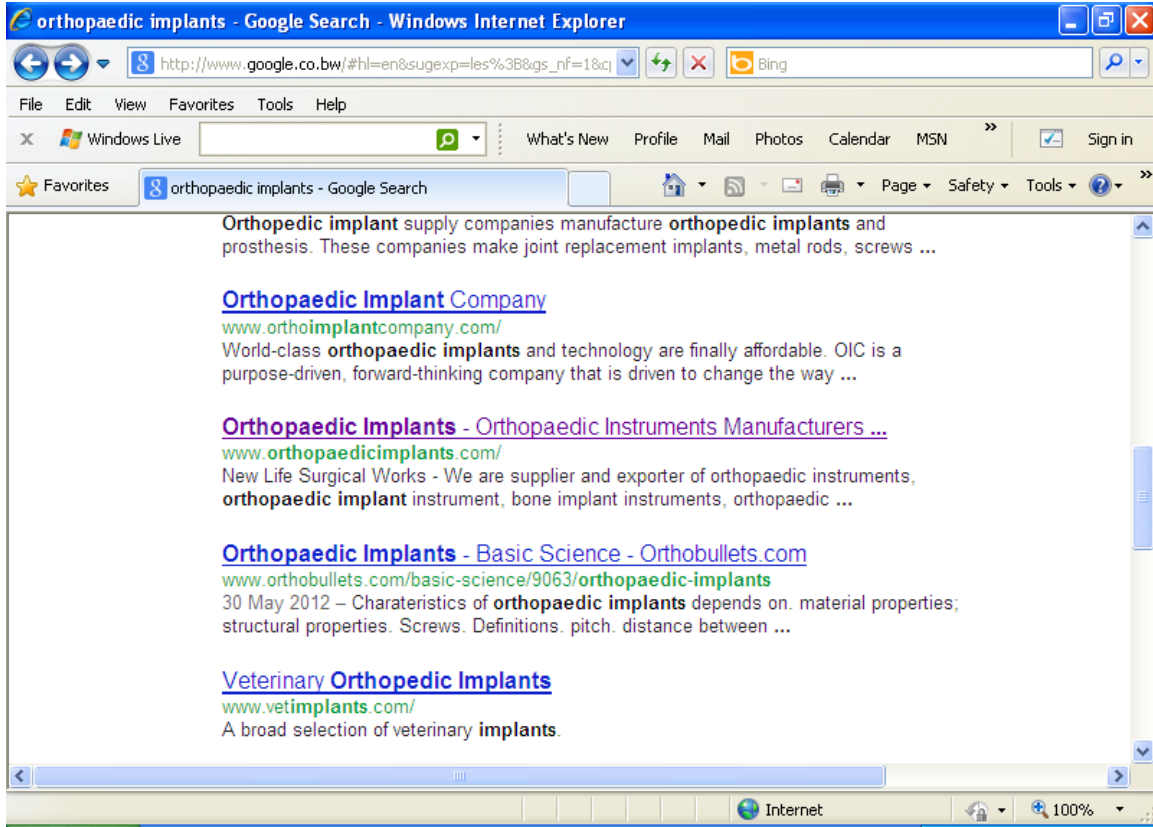


RNDr. Radomír Čevelík

RNDr. Radomír Čevelík

Issued in Zlín, on 8th October 2007

Representative of the Notified Body No. 1023



Orthopaedic Equipments - Medical Equipments, Orthopaedic Equipment Supplier, Medical Equipments S - Window...

http://www.orthopaedicimplants.com/profile.html

File Edit View Favorites Tools Help

Windows Live What's New Profile Mail Photos Calendar MSN Sign in

Orthopaedic Equipments - Medical Equipments, Orthop...

New Life Surgical Works
An ISO 9001:2000 Certified Company, CE & WHO:GMP Compliances

Exporters of all type of Orthopaedic Implants & Instruments
Exporting in 60 countries
(316 L S S)

HOME ABOUT US OUR PRODUCTS F. A. Q CONTACT US ENQUIRY

Home » Profile

About US
An ISO 9001-2000 c
India in the Manufac
instruments. Since o
preference and custome

We, at New Life make
customers, vendors, b
company, observing hi

Bone Screws
Bone Plates
Hip Prosthesis
Nails
Wires & Pin
Tubular External Fixator
Bone Drill & Wire Instruments
Bone & Plate Holding Forceps

Surgical Works is a market leader in
tor of orthopaedic implants and
we have gained tremendous brand

a long-term relationship with our
thers. The professionally managed
ted to the quality of its personnel

OUR PRODUCTS

Bone Screws

- Cancellous Screws
- Cortical Screws
- Malleolar Screws
- Schanz Screw

Bone Plates

OUR LDCS Plates

Internet 100%

Orthopaedic Equipments - Medical Equipments, Orthopaedic Equipment Supplier, Medical Equipments S - Window...


http://www.orthopaedicimplants.com/profile.html

File Edit View Favorites Tools Help


Windows Live What's New Profile Mail Photos Calendar MSN Sign in

Orthopaedic Equipments - Medical Equipments, Orthop...

Implants as per ISO-5831/1: 1997 Composition-"D". This 316-L Stainless Steel is also compatible to the International Standards Like: BS-7252/1: 1997 Composition-"D" ASTM: F-138: 1992-GR 2: & DIN-17443: 1986-1.4441.



EC CERTIFICATE
Click here for Download pdf



ISO CERTIFICATE
Click here for Download pdf

Nails

- Interlocking Nails
- Kuntscher Nails
- Orthopaedic Nails

Wires & Pin

- Wires & Pin

Tubular External Fixator

- Bone Clamps
- Box Spanner
- External Fixator

Bone Drill & Wire Instruments

- Bone Drilling Instruments
- Bone Wire Instruments

Bone & Plate Holding Forceps

- Bone & Plate Holding Forceps

Internet 100%

Orthopaedic Equipments - Medical Equipments, Orthopaedic Equipment Supplier, Medical Equipments S - Window...

http://www.orthopaedicimplants.com/profile.html

File Edit View Favorites Tools Help

Windows Live What's New Profile Mail Photos Calendar MSN Sign in



Orthopaedic Equipments - Medical Equipments, Orthop...

- Nails:** Nails are used as the method of fixation in the cases of combination of complex femoral fractures. This procedure is performed in fractures of femoral shaft associated with fracture neck femur, pathological fractures of proximal third of femur with trochanteric pathology, ipsilateral fracture of femur and tibia in polytrauma cases with multiple other injuries.
- Wires & Pin:** clavicular nonunions disorders are treated by open reduction and intramedullary Steinman pin fixation with onlay iliac crest bone grafting. The majority of nonunions occurred after high-energy injuries to the clavicle. These are used to stabilize bone fragments. These can be drilled through the bone to hold the fragments in place. They are placed percutaneously (through the skin), thus avoiding an operation in some cases.
- Tubular External Fixator:** The external fixator incorporates telescopic tubes for axial dynamization and angled bayonet screws to keep the tubes parallel to the bone axis, that is essential for gliding, and adjustment of rotation. Tubular external fixation is a safe method for treating the bone and soft tissue lesions in fractures. Dynamic fixator has a valuable part to play as a definitive mode of therapy for severe open fractures of the tibial shaft.
- Bone Drill & Wire Instruments:** These are used to penetrate cortical bone and gain access to the lesion. This eccentric drill makes a hole in the bone larger than the diameter of the cannula and thereby makes it easy to advance the cannula over the

Excellent After Sales Service

ISO CERTIFICATION

An ISO 9001-2000 Certified Company, New Life Surgical Works is a market leader in India in distributing orthopaedic implants and instruments. Since our inception in the year 1974, we have gained tremendous brand preference and customer loyalty.

Internet 100%