



Notified Body No. 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0424 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) as amended, certifies that the products – medical devices of Class IIb,

Otology Implants (OSSEOUS Surgical Implants)
(For detailed specification refer to Annex)

manufactured by company

EON MEDITECH PVT. LTD.

**403, B-Tower, Diamond World, Mangadh Chowk, Varachha Road, Surat -
395006, Gujarat, 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. 803601103/2011, 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 17th May 2016 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

Issued in Zlín, on 18th May 2011




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



**Annex to EC Certificate
No. 11 0424 QS/NB**

Issued for the company:

EON MEDITECH PVT. LTD.

**403, B-Tower, Diamond World, Mangadh Chowk, Varachha Road, Surat - 395006,
Gujarat, INDIA**

List of the medical devices covered by the EC certificate:

Variants

Tita-prosthesis type Partial Vario Campana

Tita-prosthesis type Total Vario Cask

Tita-prosthesis Piston type Loop

Tita-prosthesis Vent Tube type Collar Button

Tita-PTFE Vario Piston type Loop

Superelastic NITINOL-PTFE Vario Piston type Loop

Super Titanium Vario Piston type Loop

Super Tita-PTFE Vario Piston type Loop


PTFE Middle Ear Implants & Ventilation Tubes

TitaHAp-prosthesis type Vario Partial (PORP)

TitaHAp-prosthesis type Vario Total (TORP)

Issued in Zlín, on 18th May 2011
Valid until 17th May 2016




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023