ITC

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

EC CERTIFICATE

No. 13 0639 .QS/NB OBL

Issued in compliance with the Counc1l 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,

Internal Hex Conical Implant Assembly

Internal Hex Cylindrical Implant Assembly

Manufactured by company

OOO NPO VITADENT

26 Posadskaja str., Yfa, 450001, Russia

are manufactured-under conditions fulfilling the quality system requ1rements of Annex 11, Section 3 2 of tt1e D1rective 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 1s 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. 80360 1607/2013 which is enclosed to this Certificate.

Condition of this Certificate use and related intonation

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 28 February 2017 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 tile above referenced models, the C mark followed by the number of the Notified Body according to this example:*

Issued in Zlin, on 28/02/2013

INSTITUTE FOR TESTING AND CERTIFICATION
1023
NOTIFIED BODY

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