

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK  
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE  
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

## CE - CERTIFICATE of production quality assurance

No.: MED 110029

The Electrotechnical Testing Institute, Notified Body No. 1014, has decided that Quality System applied by

manufacturer **ZIRCONE-TECH**  
Route de la Fortunière, CHAVAGNEUX, 42170 SAINT JUST SAINT RAMBERT,  
France

for manufacture and final inspection of medical devices

**Ceramic blocks for dental use, non sterile – class IIa, see enclosure**

complies with provisions of Annex 5 section 3 of Governmental Order No. 336/2004 Coll. (Annex V section 3 of the Council Directive 93/42/EEC) incl. amendments.

This decision is based on the results presented in report No. 004878-02 of: 27.01.2011,  
200549-01 of: 21.02.2012

In accordance with Art. 5 of Governmental Order No. 336/2004 Coll. (Art. 17 of Council Directive 93/42/EEC), incl. amendments the above specified medical device must be labelled CE 1014.


The certified manufacturer is subject to a surveillance audit by the notified body in accordance with section 4 of Annex 5 of Governmental Order No. 336/2004 Coll. (Annex V section 4 of Council Directive 93/42/EEC) incl. amendments, and validity of the Certificate is subject to regular supervision. The manufacturer must inform the notified body about any intention resulting in significant modification of quality system or scope of included medical products. In the event that the conditions under which the Certificate has been issued are violated, the notified body may suspend the Certificate's validity or cancel the Certificate.

Edition 1

Date of first issue of Certificate with validity until  
**The validity of current Certificate is limited until: 11.3.2016**

11.3.2011 corrigendum 28.6.2011

Prague

  
Miroslav Sedláček  
Certification and Inspection Manager



Stamp



004878-02