Products Certification Body
Institute for Testing and Certification, Inc.
Zlin, Czech Republic – www.itczlin.cz

CERTIFICATE

No. 12 0431 V/ITC

confirms that the products – medical devices of the Class I according to the Council Directive 93/42/EEC, model

Hard alloy burs for dental laboratory

manufactured by company

„Freza" Ltd.

34, Sibirsky tract Str, building 4, 420029 Kazan, Republic of Tatarstan, Russia

applied by company:

ONKOCET, Ltd., Kutuzovova 4, 90201 Pezinok, Slovakia

is comply with the applicable essential requirements of the Council Directive 93/42/EEC on medical devices as amended.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the product-examination of the certified products according to the relevant parts of the above mentioned Directive and appropriate harmonized European standards.

Based on audit of the quality management system implemented by the manufacturer, the ITC Products Certification Body confirms a manufacturer's ability to keep permanently the requested safety and quality level. The more detailed products description, documents, assessment procedures and evaluations of the examination and of the management system audit are presented in the Final Report No. 313600307/2012, which is enclosed to this certificate.

Condition of this Certificate use and related information:

1. *It applies only to the above referenced models of the medical devices.*
2. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this Certificate.*
3. *The Certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed but until the **31st May 2015** at the latest.*
4. *The validity is conditioned by positive results of periodic surveillance audits.*
5. *After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking according to this example:*

CE

Issued in Zlín, on 24th May 2012

Institut pro testování a certifikaci, a.s. Zlín

RNDr. Radomír Čevelík
General Director