



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC Design-Examination Certificate

## No. 05 0152 CN/NB/b

issued in compliance with Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 Coll., certifies that the product – medical device of Class III

**Knitted vascular prosthesis with collagen Ra K**  
**Incompressible vascular prosthesis with collagen MF 2K**  
**Knitted vascular patch with collagen Ra ZK**  
**Knitted vascular prosthesis with collagen Ra K incompressible**

manufactured by company

**Výzkumný ústav pletářský, a.s.**  
**Šujanovo náměstí 3, 658 61 Brno, Czech Republic**  
**Tax Registration No.: CZ15546578**

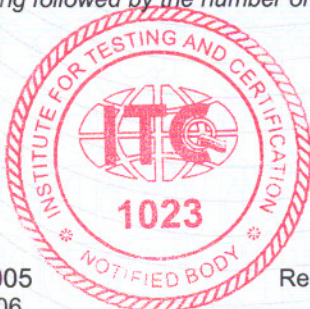
fulfils the essential requirements specified in the Annex I of the Directive 93/42/EEC relating to it, taking into account the product's intended use.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned product according to paragraph 4, Annex II of the Directive 93/42/EEC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination are presented in the Final Report No. 803600100/b/2005, 803600128/2006 and 803600401/2008, which are enclosed to this Certificate.

*This Certificate is issued under following conditions:*

- 1. It applies only to the design of above referenced model of medical device.*
- 2. It does not imply that the Notified Body has performed any surveillance or control of its manufacture.*
- 3. The Certificate remains valid until the approved design is changed but until the **28<sup>th</sup> March 2010** at the latest.*
- 4. Having in possession a complementary EC Certificate confirming the manufacturer's quality system approval by Notified Body No. 1023, the manufacturer shall affix to each medical device of the above referenced type, the CE marking followed by the number of the Notified Body according to this example:*

**CE 1023**



*RNDr. Radomír Čevelík*

**RNDr. Radomír Čevelík**

Representative of the Notified Body No. 1023

Issued in Zlín, on 29<sup>th</sup> March 2005  
Revision a) 15<sup>th</sup> February 2006  
Revision b) 22<sup>nd</sup> October 2008

(Replaces the withdrawn Certificate No. 05 0152 CN/NB/a issued on 15<sup>th</sup> February 2006)