



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

EC CERTIFICATE

No. 05 0151 QS/NB/b

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), 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

is 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 Reports No. 803600100/b/2005, 803600128/2006 and 803600401/2008 which are 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 28th March 2010 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



R. Paul Voj
RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023

Issued in Zlín, on 29th March 2005

Revision a) 15th February 2006

Revision b) 22nd October 2008

(Replaces the withdrawn Certificate No. 05 0151 QS/NB/a issued on 15th February 2006)