



NOTIFIED BODY No. 1023
Institut pro testování a certifikaci, a.s., Zlín, Czech Republic

EC CERTIFICATE

No. 05 0017 QS/NB/a

issued in compliance with Council Directive 93/42/EEC as amended, the requirements of which are implemented by the Czech Government Order No. 336/2004 Collection of laws, certifies that the product – **medical device of Class IIb**

specification overleaf

introduced into the market 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.

The Notified Body No. 1023 has performed an audit of the above product quality system. The quality system has been assessed, approved and is a subject of the 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. 803600100/a/2005 and 803600141/2006, which is an integral part of this Certificate.

Provided regular surveillance is conducted, the Certificate remains valid until the manufacturing conditions or the quality system are not changed but until **25th Januar 2010 at the latest**.

Issued in Zlín, on 26th Januar 2005
Revision a.): 24th April 2006

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



Name:

Knitted vascular prosthesis Ra (Vascular prosthesis intended for application as a substitute of arteries) **IIb**

Vascular prosthesis DK (Vascular prosthesis intended for application as a substitute of arteries) **IIb**

Mesh for surgical applications CHS 100 (Mesh for surgical applications as a substitute of tissue structures or for reinforcement of organs) **IIb**

Mesh for surgical applications CHS 100P (Mesh for surgical applications as a substitute of tissue structures or for reinforcement of organs) **IIb**

CORTEX - Implantable reinforcing felt for surgical purposes (Implantable reinforcing felt for surgical purposes) **IIb**

Combined dressing textile COM 30 (Combined dressing textile designed for treatment of burns) **IIb**

Gastric bandage Ra gb (Gastric bandage designed for reduction of weight of obese patients) **IIb**

Dressing textile SANAVEL 1,2,3 (High-porous hydrophobic dressing) **IIb**

Gastric bandage Ra gp [without opening] (Gastric bandage designed for reduction of weight of obese patients) **IIb**

Mesh for urological applications - CHS URO **IIb**

Palvo

