

Výzkumný ústav pletařský, a.s.	METEA Division Technical-technological documentation to the product: <b>Knitted vascular prosthesis with collagen - Ra K</b>	Identification No.: 20.02.06/12.07 Annex No.: 20.02.07/01.07
Brno	<b>EC Declaration of Conformity</b>	Page: 1 of 1

Pursuant to § 13, subsection 2, of the Act No. 22/1997 Coll. on technical requirements for products and on amendment of some Acts in the wording of the Act No. 71/2000 Coll., the Act No. 102/2001 Coll., the Act No. 205/2002 Coll. and the Act No. 226/2003 Coll., and pursuant to § 9 of the Government Decree No. 336/2004 Coll. setting technical requirements for medical devices, and pursuant to the Directive 93/42/EEC.

The manufacturer:  
VÝZKUMNÝ ÚSTAV PLETAŘSKÝ a.s.  
Šujanovo náměstí 3  
602 00 BRNO  
Czech Republic  
Identification No. 15546578

hereby declares that the product

**Knitted vascular prosthesis with collagen – Ra K**

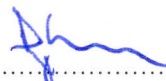
intended for application: as a substitute of arteries  
classified according to the classification of medial devices pursuant to the GD No. 336/2004 Coll. as class: **III**  
meets the essential requirements and in normal use for its purpose it is safe, effective and suitable for use in health care. The manufacturer has taken measures with which he secures the conformity of this medical device, introduced to the market, with its technical documentation (TTD **02** ) and with the essential requirements.  
To evaluate the basic properties of the product in the specified way a NB procedure was used according to Annex No. 2, including article 4, GD No. 336/2004 Coll., with participation of the NB No. 1023 ITC a.s., Zlín.

Fulfilment of the procedure is documented by:

- Certificate No. 06 0178 SJ of 18.12. 2006 on established, documented and implemented quality management system according to ČSN EN ISO 9001:2001 for Research, manufacture and distribution of textile based medical devices, issued by the certification body No. 3002 ITC a.s. Zlín, Czech Republic
- Certificate No. 06 0179 of 18.12. 2006 on established, documented and implemented quality management system according to ČSN EN ISO 13485:2003 for Research, manufacture and distribution of textile based medical devices, issued by the certification body No. 3002 ITC a.s. Zlín, Czech Republic
- Certificate No. č.CQS 2023/2007 documenting that the quality system complies with the requirements of the ČSN EN ISO 9001:2001 for the processes of Research, manufacture and distribution of textile based medical devices, issued by the certification body CQS Praha, Czech Republic
- Certificate No. CQS 19/2007 documenting that the quality system complies with the requirements of the ČSN EN ISO 13485:2003 for the processes of Research, manufacture and distribution of textile based medical devices, issued by the certification body CQS Praha, Czech Republic
- Certificate No. CZ-2023/2007 documenting that the quality system complies with the requirements of ISO 9001:2000 for the processes of Research, manufacture and distribution of textile based medical devices, issued by the certification body IQNet
- Certificate No. CZ-19/2007 documenting that the quality system complies with the requirements of ISO 13485:2003 for the processes of Research, manufacture and distribution of textile based medical devices, issued by the certification body IQNet
- EC Certificate No. 05 0151 QS/NB and EC Design-Examination Certificate No. 05 0152 CN/NB of 29.3.2005 issued by the NB No. 1023 ITC a.s., Zlín

Brno: 12.12.2007

8<sup>th</sup> edition

  
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Ing. Ivan Dyba  
managing director

**Výzkumný ústav pletařský, a.s.**



Šujanovo nám. 3  
602 00 Brno  
Česká republika

No. 004750 E **Brno** 17-12-2008

**SEEN**



*Zwibov*  
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