

VÚP a.s. Brno	METEA Division Technical-Technological Documentation to the product: CORTEX Implantable reinforcing felt for surgical applications EC Declaration of conformity	Identification No. 05.07.05/12.07 Annex No. 3 Page 1 of 1
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Pursuant to § 13 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. 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
Company registration No.: 15546578

hereby declares that the product

CORTEX - Implantable reinforcing felt for surgical applications

intended for application as an implantable reinforcing felt serving as a support under sutures preventing a cutting through of the tissue in surgical operations,
classified according to the classification of medical devices as class: II b,
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 into the market, with its technical documentation (TTD 07) and with the essential requirements.
To evaluate the basic properties of the product in the specified way a procedure was used according to Annex No. II, excluding article 4, GD No. 336/2004 Coll., with participation of the NB No. 1023 ITC a.s., Zlín.

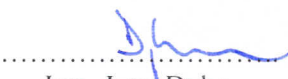
Fulfilment of the procedure is documented by:

- Certificate No. 06 0178 SJ of 18.12.2006 on established, documented and implemented quality system according to ČSN EN ISO 9001 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 13 485 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. CQS 2023/2007 documenting that the quality system complies with the requirements of ČSN EN ISO 9001 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 ČSN EN ISO 13 485 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 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 13 485 for the processes of Research, manufacture and distribution of textile based medical devices, issued by the certification body IQNet
- EC Certificate No. 050017 QS/NB of 26.1.2005 issued by the NB No. 1023 ITC a.s., Zlín

Brno : 12.12. 2007

Výzkumný ústav pletařský, a.s.

 Šujanovo nám. 3
 602 00 Brno
 Česká republika


 Ing. Ivan Dyba
 company director

No. 004750 A Brno 17-12-2008

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Zwiebová

Česká republika
Brno
17-12-2008