

Výzkumný ústav pletařský a.s. Brno	METEA Division Technical-Technological Documentation to the product: ARAVEL medical underwear EC Declaration of conformity	Identification No. 20.25.04/12.07 Annex No.: 3 Page 1 of 1
------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------

Pursuant to § 13, clause 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. 205/2002 Coll., 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
65861 BRNO, Czech Republic
Company registration No.: 15546578

hereby declares that the product

ARAVEL medical underwear

intended for application as a non-sterile medical device – medical underwear, classified according to the classification of medical devices pursuant to the GD No. 336/2004 Coll. as class I (non-sterile product) 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 25) and with the essential requirements. To assess the basic properties of the product in the specified way a procedure was used according to Annex No. 7, GD 336/2004 Coll.

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 13485 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
- Clinical expert opinion of 26.6.2003

Brno : 12.12.2007

OVĚŘENÍ VIDIMACE
Ověřuji, že tento opis složený z jednoho listu
doslovně souhlasí s listinou, z níž
byl pořízen, složenou z jednoho listu

Edition: N°5



V Brně, dne - 5 - 12 - 2008

Lenka Skoumalová
notářská tajemnice
pověřená notářem v Brně

Ing. Ivan Dyba
company director

Výzkumný ústav pletařský, a.s.



Šujanovo nám. 3
602 00 Brno
Česká republika

MINISTERSTVO SPRAVEDLNOSTI ČR V PRAZE

Čís. leg. rej. 26911/2008
Pravost předchozího podpisu a úřední
pečeti se tímto potvrzuje

V Praze dne 8-12-2008

Za ministra

Jana Stejskalova



**MINISTERSTVO ZAHRANIČNÍCH VĚCÍ
ČESKÉ REPUBLIKY**

Č. leg. rej. 5907 2008

Pravost předchozího podpisu a úřední
pečeti se potvrzuje. 08-12-2008

V Praze dne 2008

Vedoucí oddělení

J. Turková
Jatoslava Turková



Embassy of the Arab Republic of Egypt
in Prague
(Consular Section)

Seen for legalization of the signature of
Mr. *J. Turková*
and of the seal of the Czech Ministry of
Foreign Affairs

Legalization No. -1189-

Fees collected 2.250,- CZK

Date 12-12-2008

