



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC Design-Examination Certificate

## No. 10 0423 CN/NB/b

issued in compliance with Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class III

**Knitted vascular patch with collagen Ra ZK**  
**Knitted vascular prosthesis with collagen Ra K**  
**Knitted vascular prosthesis with collagen Ra K Incompressible**

manufactured by company

**VUP Medical, a.s.**

**Šujanovo náměstí 3, 602 00 Brno, Czech Republic**

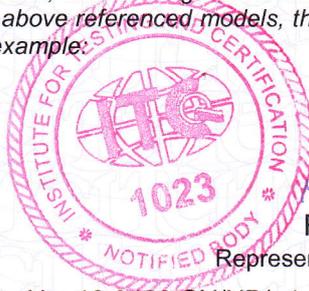
fulfil the essential requirements specified in the Annex I of the Directive 93/42/EEC and Regulation (EU) No. 722/2012 relating to it, taking into account the product's intended use.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned products according to the Annex II, paragraph 4, of the Directive 93/42/EEC and Article 5 of the Directive 2003/32/EC. The detailed products description, documents, assessment procedures and evaluation of the examination are presented in the Final Reports No.803600811/2010, No.343602382/2014 and No.803602394/2015, which are enclosed to this Certificate.

*Condition of this Certificate use and related information:*

- 1. It applies only to the design of the above referenced models of the medical devices.*
- 2. It does not imply that the Notified Body has performed any surveillance or control of their manufacture.*
- 3. The manufacturer is obligated to assure that all medical devices of the respective models conform to the type whose design has been approved by this Certificate.*
- 4. The Certificate remains valid until the approved design is changed but until the 18<sup>th</sup> May 2017 at the latest.*
- 5. After receiving of the complementary EC Certificate, confirming the manufacturer's quality system approval by the Notified Body No. 1023, and 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**



*Paul Vaj*

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

Issued in Zlín, on 23<sup>rd</sup> March 2015

Replaces the withdrawn EC Certificate No. 10 0423 CN/NB/a issued on 4<sup>th</sup> April 2014