



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Full Quality Assurance System No. 18 0476 QS/NB

The quality system of manufacturer

**VUP Medical, a.s.**

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

has been certified as meeting the requirements of

**Directive 93/42/EEC**

**on medical devices, Annex II excluding (4)**

for the following product category(ies):

**Wound Dressing**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

**Valid from:** 2018-10-12

**Valid until:** 2023-10-11

**First Issued:** 2018-10-12

**Revision:** -

Date: 2018-10-12



**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Certificate No. 18 0476 QS/NB

issued for manufacturer:

**VUP Medical, a.s.**  
**Šujanovo náměstí 3, 602 00 Brno, Czech Republic**

### Product(s):

**Name:** Combined dressing fabric COM 30

**Trade name(s):** -

**Model(s):** 100mm × 75mm (Cat. No. 140 – 1075)  
150mm × 100mm (Cat. No. 140 – 1510)  
200mm × 150mm (Cat. No. 140 – 2015)  
300mm × 200mm (Cat. No. 140 – 3020)  
300mm × 400mm (Cat. No. 140 – 3040)

**Class:** IIb

**GMDN:** 44970

**Name:** Dressing textile SANAVEL 1

**Trade name(s):** -

**Model(s):** 140mm × 100mm (Cat. No. 131 – 1410)

**Class:** IIb

**GMDN:** 46855

**Name:** Dressing textile SANAVEL 2

**Trade name(s):** -

**Model(s):** 140mm × 100mm (Cat. No. 132 – 1410)

**Class:** IIb

**GMDN:** 46855

Date: 2018-10-12

Revision: -



**Mgr. Jiří Heš**

Representative of the Notified Body No. 1023



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

**Annex to EC Certificate No. 18 0476 QS/NB**  
issued for manufacturer:

**VUP Medical, a.s.**  
**Šujanovo náměstí 3, 602 00 Brno, Czech Republic**

**Facility(ies):**

VUP Medical, a.s.  
Šujanovo náměstí 3, 602 00 Brno, Czech Republic

**Certificate History:**

Revision	Date	Reference Number	Action
-	2018-10-12	803602568	Certification

Date: 2018-10-12  
Revision: -



**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023