



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



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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



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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: -



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