



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. 17 0076 QS/NB

The quality system of manufacturer

I.V.T. Medical Ltd.

16 Hatidhar st., Ra'anana, 4366518, Israel

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):

TopClosure® Tension Relief System

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. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with securing and maintaining sterile conditions. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

Valid from: 2017-02-28


Valid until: 2022-02-27

First Issued: 2017-02-28

Revision: -

Date: 2017-02-28




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



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Annex to EC Certificate No. 17 0076 QS/NB

issued for manufacturer:

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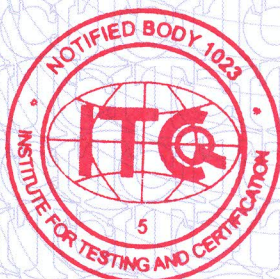
Product(s):

Name:	TopClosure® Tension Relief System
Trade name(s):	TopClosure®
Model(s):	3S Hospital Pack, 1S Clinic Pack, 1S-AD First-Aid Kit, 1S-M Rescue Kit
Class:	Is
GMDN:	33873

Facility(ies):

I.V.T. Medical Ltd.
16 Hatidhar st., Ra'anana, 4366518, Israel

Date: 2017-02-28
Revision: -



Paul Voj
RNDr. Radomír Čevelík
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Certificate History:

Revision	Date	Reference Number	Action
	2017-02-28	803602489	Certification

Date: 2017-02-28
Revision: -



Paul Včelík
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