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. 14 0725 QS/NB

The quality system of manufacturer

VH Pharma a.s.

Jakubská 647/2, 110 00 Prague 1, 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):

HemaGel® - hydrophilic gel for wound healing
Anorectal mucosa suppository

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: 2017-06-30
Valid until: 2019-12-15
First Issued: 2014-12-16
Revision: d

Date: 2017-06-30

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RNDr. Radomír Čevelík
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. 14 0725 QS/NB

issued for manufacturer:

VH Pharma a.s.
Jakubská 647/2, 110 00 Prague 1, Czech Republic

Product(s):

Name:	**HemaGel® - hydrophilic gel for wound healing**
Trade name(s):	HemaGel® Wundprosan UniGel Apotex
Model(s):	5 g, 10 g, 30 g, 100 g, 250 g
Class:	IIb
GMDN:	47764

Name:	**Anorectal mucosa suppository**
Trade name(s):	HemaGel® procto Wundprosan procto UniGel Apotex procto
Model(s):	2g x 5 pcs, 2g x 10 pcs
Class:	IIb
GMDN:	47672

Date: 2017-06-30
Revision: d

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