



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

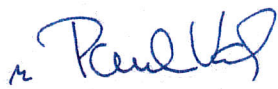
**Valid until:** 2019-12-15

**First Issued:** 2014-12-16

**Revision:** d

Date: 2017-06-30



  
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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