



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 14 0725 QS/NB/b

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws), certifies that the products – medical devices of Class IIb

HemaGel® - hydrophilic gel for wound healing

additional trade names: **Wundprosan**
UniGel Apotex

HemaGel® procto

additional trade names: **Wundprosan procto**
UniGel Apotex procto

manufactured by company

VH Pharma a.s.

Jakubská 647/2, 110 00 Praha 1, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Reports No. 803602306/2014, No. 803602386/2015 and No. 803602479/2016, which are enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 15th December 2019 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023



Paul Vaj
RNDr. Radomír Čevelík
Representative of the Notified Body No. 102

Issued in Zlín, on 12th February 2016

Replaces the withdrawn EC Certificate No. 14 0725 QS/NB/a issued on 24th March 2015