

Manufacturer:

## **VH PHARMA a.s.**

Registered office at: *Jakubská 647/2, 110 00 Praha 1, Czech Republic*

Place of business: *Arbesova 797/III, 337 01 Rokycany, Czech Republic*

Identification number: *280 89 529*

*Issued pursuant to Act No. 268/2014 Sb. on medical devices, in conjunction with Government Decree No. 54/2015 Coll. on technical requirements for medical devices, in accordance with Act No. 22/1997 Coll. on technical requirements for products and Council Directive 93/42 / EC on medical devices.*

## **DECLARATION OF CONFORMITY**

*Declaration number: H – 4/0/21*

*and declares at its sole responsibility that the medical device*

***HemaGel<sup>®</sup>, UniGel AUROVITAS<sup>®</sup>, UniGel,  
WundPROsan<sup>®</sup>, Healit, HemaRos,***

*Intended purpose: hydrophilic gel for superficial skin injury treatment*

*Class of medical device: IIa*

*Classification rule 4 according to Government Decree No. 54/2015 Coll. And on the basis of Act No. 268/2014 Coll.*

*Notified body: Institute for Testing and Certification Inc., No. 1023, registered office at T. Bati 299, Louky, 763 02 Zlín*


*Certificate No.: 19 0404 QS\_NB rev.b*

*The certificate is valid until: May 27, 2024*

*The manufacturer declares that the properties of the above-mentioned medical device comply With all the requirements set by Act No. 268/2014 Coll., in accordance with Government Decree No. 54/2015 Coll. and Directive 93/42 / EC, that the medical device is safe and effective for its intended purpose and suitable for providing health care. Furthermore, the manufacturer declares, that it has taken measures to ensure compliance of the medical device being introduced onto the market with the elementary requirements and technical documetation of the manufacturer and with the applicable harmonized standards in force – ČSN EN ISO 13 485 ed.2:2016, ČSN EN ISO 14 971:2012, ČSN EN ISO 14 155:2012, ČSN EN ISO 62366-1:2019, ČSN EN ISO 10 993-1:2010, ČSN EN ISO 9001:2016, ČSN EN ISO 9000:2016, ČSN EN ISO 10 993-5:2010*

Prague, dated *17.10.2022*

*Ing. Bohumil Hána*  
Chairman of the Board

**VH Pharma a.s.**  
Jakubská 647/2  
Staré Město, 110 00 Praha 1  
IČ: 280 89 529 

**Ověření - legalizace**

Ověřuji, že pod pořadovým číslem 11X61J3 tuto listinu přede mnou vlastnoručně podepsala níže uvedená osoba, jejíž totožnost byla prokázána:  
Bohumil Hána, nar. 14.07.1984, Šeříková 324/12, 32600 Plzeň - Koterov.  
Rokycany, dne 11.10.2022



*Pavla Bučková*

**Mgr. Pavla Bučková**  
**notářka v Rokycanech**

