



**EC Certificate – Production Quality Assurance**  
**Directive 93/42/EEC on Medical Devices, Annex V**  
**Certificate No. MDD-042**

Issued to: JADRAN - GALENSKI LABORATORIJ d.d.  
Svilno 20, 51000 Rijeka, Croatia  
Place of production: JADRAN - GALENSKI LABORATORIJ d.d.  
Svilno 20, 51000 Rijeka, Croatia  
Product category: Eye drops  
GMDN: 44237

SIQ has audited the quality system in accordance with MDD Annex V and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on

Audit report No.:  
OSV 00981/2015, 2015-12-22  
OSV 01333/2017, 2018-01-25  
OSV 00032/2019, 2019-01-31  
OSV 00041/2019, 2019-01-31

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4) and continues to meet the above requirements.

Certification date: 2012-12-28

Issue: 04/2019-01-31

Valid until: 2024-01-31



Director of SIQ

Igor Likar



Z vami več kot  
With you for over  
**50** let  
years  
o o o

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Mrs  
Vedrana Despot Štefanović  
JADRAN - GALENSKI LABORATORIJ d.d.  
Svilno 20  
51000 RIJEKA  
HRVATSKA

vaš znak / your ref.: OSV/4339

naš znak / our ref.: 2019-02-01

datum / date:

Dear Mrs Despot Štefanović!

We would like to inform you that the Notified Body Commission for medical devices adopted the following decision at its last meeting:

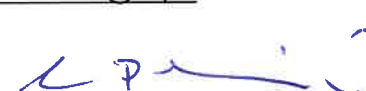
On the basis of technical documentation audit report (OSV 00041/2019, dated 2019-01-31), re-certification audit report (OSV 00032/2019, dated 2019-01-31), technical documentation audit report (OSV 01333/2017, dated 2018-01-25) and post-audit report (OSV 00981/2015, dated 2015-12-22) the current edition of MDD-042 certificate (03/2015-12-28) is cancelled and the new edition is issued:

Certificate No.: **MDD - 042**  
Issued to: JADRAN - GALENSKI LABORATORIJ d.d.  
Svilno 20, 51000 Rijeka, Croatia  
Place of production: JADRAN - GALENSKI LABORATORIJ d.d.  
Svilno 20, 51000 Rijeka, Croatia  
Product category: Eye drops  
GMDN: 44237  
Standard: MDD 93/42/EEC  
Annex: V  
Kategorija proizvoda: Očne kapi  
GMDN: 44237  
Certification date: 2012-12-28  
Issue: 04/2019-01-31  
Valid until: 2024-01-31

Detailed list of product names, models and types:

Certificate No.: **MDD-042**  
Issued to: JADRAN - GALENSKI LABORATORIJ d.d.,  
Svilno 20, 51000 Rijeka, Croatia  
Product category: Eye drops/  
Očne kapi  
GMDN: 44237  
Classification: IIa  
Product name: Vizol S 0.10% eye drops, solution  
Alternative name: Sodium hyaluronate 0.1% eye drops, solution  
Optinol 0.10% eye drops, solution  
Winocul 0.10% eye drops, solution  
XEDRENIO  
HYAZOL 0.21% eye drops, solution  
Model/Type: 10 ml  
Product name: Vizol S 0.21% eye drops, solution  
Alternative name: Sodium hyaluronate 0.21% eye drops, solution  
Optinol 0.21% eye drops, solution  
Winocul 0.21% eye drops, solution  
Belcils MED eye drops, solution (sodium hyluronate 0.21%)  
Model/Type: 10 ml  
Product name: Vizol S 0.40% eye drops, solution  
Alternative name: Sodium hyaluronate 0.40% eye drops, solution  
Optinol 0.40% eye drops, solution  
Winocul 0.40% eye drops, solution  
Belcils MED eye drops, solution (sodium hyluronate 0.40%)  
XEDRENIO Forte  
HYAZOL 0.40% eye drops, solution  
Model/Type: 10 ml  
Standard: MDD 93/42/EEC  
Date of issuing the list: 2019-01-31  
Valid until: 2024-01-31

For all further information we are available on telephone number 00 386 1 4778 159 and email:  
[vesna.rems@siq.si](mailto:vesna.rems@siq.si).

  
Management Systems Assessment  
Medical Devices – Product manager  
Ana Pribaković Borštnik