

BUREAU VERITAS
Certification



JADRAN - GALENSKI LABORATORIJ d.d.

Svilno 20, 51000 Rijeka, Croatia

Multisite certificate. Certified sites are listed in the appendix to this certificate
Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

EN ISO 13485:2016

Scope of certification

Development, manufacturing and wholesale of sterile solutions (nasal drops and sprays, eye drops, ear sprays, throat sprays), solutions for oral administration, pressurised preparations (aerosols for nose, throat, ear), nasal irrigation solution system, solid oral forms, suppositories, gels and capsules for vaginal application, gels for topical use.


Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

Original cycle start date:	22 July 2010
Expiry date of previous cycle:	06 July 2019
Certification / Recertification Audit date:	20 - 24 May 2019
Certification / Recertification cycle start date:	15 July 2019

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **15 July 2022**

Certificate No. - Version: IT284034 - 1

Revision date: 15 July 2019


ANDREA FILIPPI - Local Technical Manager

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it



SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

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*Attachment to the Certificate of Conformity
N° IT284034*

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Svilno 20, 51000 Rijeka, Croatia

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EN ISO 13485:2016

Certified Sites

Site	Address	Scope
Operative Site	Svilno 20, 51000, Rijeka, Croatia	Development, manufacturing and wholesale of sterile solutions (nasal drops and sprays, eye drops, ear sprays, throat sprays), solutions for oral administration, pressurised preparations (aerosols for nose, throat, ear), nasal irrigation solution system, solid oral forms, suppositories, gels and capsules for vaginal application, gels for topical use.
Operative Unit	Pulac 4a, 51000, Rijeka, Croatia	Development of sterile solutions (nasal drops and sprays, eye drops, ear sprays, throat sprays), solutions for oral administration, pressurised preparations (aerosols for nose, throat, ear), nasal irrigation solution system, solid oral forms, suppositories, gels and capsules for vaginal application, gels for topical use.

Version No. 1

Revision date: **15 July 2019**


ANDREA FILIPPI – Local Technical Manager

Certification body address:
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