



EC CERTIFICATE

Certificate No 2012/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V of the Directive 93/42/EEC and its revised version, we hereby certify that:

NIRIAL PHARMA SRL

20145 MILANO (MI) - VIA LORENZO MASCHERONI 27/29 (ITA) - Italy

manages in the factory of:

20145 MILANO (MI) - VIA LORENZO MASCHERONI 27/29 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Protective spray for damaged skin

series and type refs in the Annex

with relevant essential requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V. For class IIb and III devices, this certificate is valid only with relevant EC Type-Examination certificate of Annex III.

Reference to IMQ files Nos:

DM18-0030080-01; DM19-0044994-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2018-10-19
Updated: 2019-11-19
Substitution Date: 2018-10-19
Expiry Date: 2023-10-18


IMQ

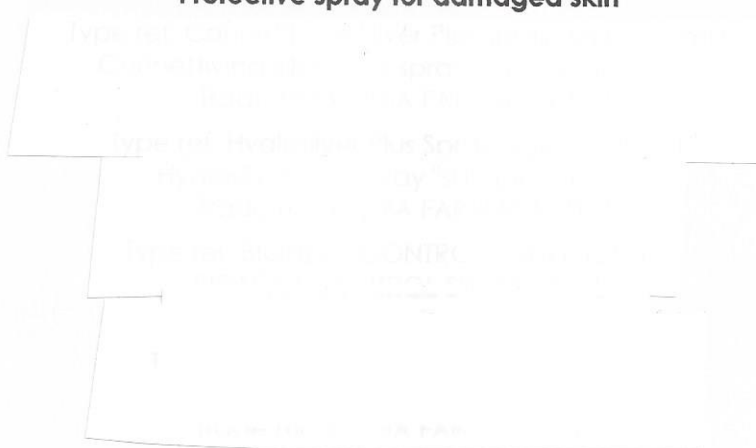


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Annex

Protective spray for damaged skin



Type ref. SILBEN NANO REPAIR "sale" (125 mL);
SILBEN NANO REPAIR "sample" (125 mL)
Trade mark EPSILON HEALTH

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