CERTIFICATE

EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-19-592

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

PHARMA LABS S.R.L

Via Magenta 106 – 71016 San Severo (FG), Italy

Product: Sodium Hyaluronate for intra- articular use
Model Name: Synart 40 mg/2ml, Synart 80 mg/4ml, Relynart 40 mg/2ml, Relynart 80 mg/4ml, Synart 24 mg/2ml, Relynart 24 mg/2ml, Synart 30 mg/2ml, Relynart 30 mg/2ml, Synart 60 mg/4ml, Relynart 60 mg/4ml
The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.5521.01
Expiry Date: 24 April 2024
Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

25 April 2019, Istanbul, Turkey

Head of Notified Body

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