Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 13 0625 QS/NB

Issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the product – medical device of Class III

Modified Sodium Hyaluronate Gel for Injection

Model: **2ml**

manufactured by company

Shandong Gallop Bio-Engineering Co., Ltd.

Zhangqiu Shengjing High-tech Industrial Park, Jinan, Shandong Province, China

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601891/2013, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of the medical devices and it does not substitute the design or type-examination procedures.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **15th July 2020** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling of the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 16th July 2013

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC Design-Examination Certificate

No. 13 0626 CN/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the product – medical device of Class III, type

Modified Sodium Hyaluronate Gel for Injection

Model: **2ml**

manufactured by company

Shandong Gallop Bio-Engineering Co., Ltd.

Zhangqiu Shengjing High-tech Industrial Park, Jinan, Shandong Province, China

fulfils the essential requirements specified in the Annex I of the Directive 93/42/EEC relating to it, taking into account the product's intended use.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned product according to the Annex II, paragraph 4, of the Directive 93/42/EEC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination are presented in the Final Report No. 803601891/2013, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the design of the above referenced models of the medical devices.*
2. *It does not imply that the Notified Body has performed any surveillance or control of their manufacture.*
3. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type whose design has been approved by this Certificate.*
4. *The Certificate remains valid until the approved design is changed but until the **15th July 2020** at the latest.*
5. *After receiving of the complementary EC Certificate, confirming the manufacturer's quality system approval by the Notified Body No. 1023, and fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 16th July 2013

INSTITUTE FOR TESTING AND CERTIFICATION * NOTIFIED BODY * 1023

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023