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

EC CERTIFICATE

No. 11 0437 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**

Hyfil
Sodium Hyaluronate Sterile Injection 0.5 ml and 1.0 ml

manufactured by company

VIRCHOW BIOTECH PVT. LTD.
Survey No. 172, (PART) Gagillapur, Qutubullapur Mandal, RR District, Hyderabad, Andhra Pradesh, India

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 is presented in the Final Report No. 803601075/2011, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

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 **2nd June 2016** 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 3rd June 2011

INSTITUTE FOR TESTING AND CERTIFICATION * NOTIFIED BODY * 1023

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