



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

EC CERTIFICATE

No. 08 0821 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 products – medical devices of Class Is, models

Surgical Disposable Wears

(Surgical Gown, Suits, Examination / Protective Apparels, Surgical Packs, Surgical Drapes, Equipment Covers)

manufactured by company

Surgeine Healthcare (India) Pvt. Ltd.

H.O.: 101, Vardhman TRU Plaza, CU Block, Pitampura, New Delhi-110088, India
Factory: J-4, Sector-1, Bawana Industrial Area, New Delhi, India

are manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2., of the Directive 93/42/EEC.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system, concerning aspects aimed to securing and maintaining of sterile conditions. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, and Annex VII, Section 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. 803600454/2008, 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 medical devices and it does not substitute the design or type-examination procedures, if requested.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 4th December 2013 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. After fulfilling the relevant EU legislation requirements, 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



R. Radomir Čevelík

RNDR. Radomír Čevelík

Representative of the Notified Body No. 1023

Issued in Zlín, on 5th December 2008