



Products Certification Body
Institute for Testing and Certification, Inc. (ITC), Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 08 0818 V/ITC

confirms that the products – medical devices of the Class I according to the Council Directive 93/42/EEC, models

Safety Products (Face Mask, Shoe Cover, Gloves, Cap)

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

comply to the applicable essential requirements of the Directive 93/42/EEC.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the type-examination of the certified product according to relevant parts of the above mentioned Directive and appropriate harmonized European standards.

Based on the audit of the quality management system implemented by the manufacturer according to the harmonized standard EN ISO 13485:2003, the ITC Products Certification Body confirms a manufacturer's ability to keep permanently the requested safety and quality level.

The more detailed product description, documents, assessment procedures and evaluations of the type-examination and of the management system audit are presented in the Final Report No. 313600157/2008, which is enclosed to this certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the above referenced models of the medical devices.*
2. *The manufacturer is obligated to assure conformity of all medical devices of the respective model to the type assessed by the mean of this Certificate.*
3. *The Certificate validity is conditioned by positive results of periodic 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 according to the following example:*



Issued in Zlín, on 5th December 2008



RNDr. Radomír Čevelík
General Director