



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

EC CERTIFICATE

No. 11 0989 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 IIa and Class I sterile

Surgical Rubber Gloves - Powdered (Sterile), brand Pristeen	IIa
Surgical Rubber Gloves - Powder Free (Sterile), brand Pristeen	IIa
Examination Rubber Gloves - Powdered (Sterile), brand Hanz On	Is
Examination Rubber Gloves - Powder Free (Sterile), brand Hanz On	Is

manufactured by company

Puritex Manufacturer Sdn Bhd

**No.54, Jalan Industri PBP 3, Taman Industri Pusat Bandar Puchong,
47100 Selangor, Malaysia.**

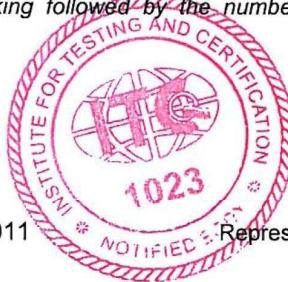
are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. 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. 803601320/2011, 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 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 17th November 2016 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After 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



Paul Voj

RNDr. Radomír Čevelík

Issued in Zlin, on 18th November 2011

Representative of the Notified Body No. 1023