



ADEN MEDİKAL CİHAZLAR VE ALETLER
İTHALAT İHRACAT PAZARLAMA SAN. VE TİC. LTD. ŞTİ.

EC Declaration of Conformity

issued in accordance with EC directive 93/42/EEC relating to Medical Devices

Manufacturer: Aden Medikal Cihazlar ve Aletler İthalat İhracat Pazarlama San. Tic. Ltd. Şti.

Address: Otagtepe Cad. No.13/A,
Kavacik / ISTANBUL
TURKIYE

Product name: Dr.Green's

Product description: Product is designed to Sterile Surgical Gowns and Drapes

Applied directives: The Directive 93/42/EEC on medical devices, conformity assessment according to Annex VII (as a Class I sterile device)

Applied harmonized standards: EN 13795-2, EN 14971, EN 980

EC Representative Name: Sefer YESILYURT

EC Representative Address: Endrestasse Nr.10 90441, Nurnberg / GERMANY

The company ADEN MEDİKAL CİHAZLAR VE ALETLER İTHALAT İHRACAT PAZARLAMA SAN. VE TİC. LTD. ŞTİ. herewith declares that the above-mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has implemented measures assuring that all products of the above mentioned type are safe and fulfil essential requirements of the 93/42/EEC Directive.

The company has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: 12st July, 2008

Havva ATMACA, President
On Behalf of Company Co.