TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II excluding (4)

Full Quality Assurance System

Medical Devices

Registration No.: **OH 69248716 0001**

Replaces certificate: OH 69240941 0001

Report No.: **28223143 001**

Manufacturer:

Medpack LLC
Str. Peredovaya 775-d
49082 Dniepropetrovsk
Ukraine

EC Representative:

MEDPACK SWISS GmbH
Tramstrasse, 16 CH-9442 Berneck,
SWITZERLAND,

Products:

GMDN code	Name
45137	Latex Condoms

The Notified Body audited the quality system and certifies that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned directive. For placing on the market of Class III devices covered by this certificate, an EC design-examination certificate according to Annex II (4) is required.

Issue Date: 2015-01-15

Effective Date: 2015-01-15

Expiry Date: 2016-06-15

Notified Body

TÜV Rheinland InterCert Kft. TÜVRheinland 5 Notified Body 1008

Zoltán Ambrus MD.

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.