

EC DECLARATION OF CONFORMITY

Manufacturer: **88/8 Moo.12 Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180 Thailand
Tel : +66 74 584 222
Fax: +66 74 584 223**

declares under its sole responsibility that non-sterile examination and protective gloves:

Type	Brand	Sizes
natural rubber latex, powder free, with inner polymer coating, for single use	dermagel® coated	XS (5-6); S (6-7); M (7-8); L (8-9); XL (9-10)

classified as **Medical device, Class I**
according to Rule 4 of Annex IX of the Council Directive 93/42/EEC

conform the applicable essential requirements of **Council Directive 93/42/EEC** amended by Directive 2007/47/EC and the European harmonized standards: EN 455, EN 980, EN 1041.
Conformity assessment procedure of the medical device according to: Annex I and Annex VII of Council Directive 93/42/EEC.

The gloves, described above, classified as **Personal Protective Equipment, Category III** are in conformity with the provisions of **Council Directive 89/686/EEC** and with the European harmonized standards: EN 420, EN 374-1 (excluding clause 5.3.2), EN 374-2 EN 374-3, EN 388.

The gloves, described above, are identical to the Personal Protective Equipment which is subject to the EC Type Examination Certificate Number 7373 (Issue 4, Extension 2) issued by:
SATRA Technology Centre, Notified Body 0321
Wyndham Way, Kettering, Northamptonshire, NN16 8SD, UK

and are subject to the procedure set out in Article 11A of Council Directive 89/686/EEC under the supervision of:
SATRA Technology Centre, Notified Body 0321
Wyndham Way, Kettering, Northamptonshire, NN16 8SD, UK.

Issue date: 16.06.2017

Signed on behalf of the Manufacturer:



Mr. Dariusz Jan Krezymon
Managing Director
Mercator Medical (Thailand), Ltd