

EC DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKÓW, POLSKA

We hereby declare under our sole responsibility that the examination gloves:

Type	Brand	Sizes
Powder free nitrile gloves	nitrylex PF	Sizes: 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/ECC

- meet the essential requirements of the **Council Directive 93/42/EEC** amended by the Directive 2007/47/EC. Conformity assessment procedure of the medical device according to : Annex I and Annex VII of the Council Directive 93/42/EEC.

The above-described product is also classified as **Personal Protective Equipment, Category III**

- is in conformity with the provisions of the **Council Directive 89/686/EEC**.

This product is identical to the Personal Protective Equipment which was subject to the EC Type Examination Certificate Number 6716 issued by:

SATRA Technology Centre, the Notified Body with identification number 0321

Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom

is product is subject to the procedure set out in Article 11B of the Council Directive 89/686/EEC under the supervision of the following Notified Body:

SATRA Technology Centre, the Notified Body with identification number 0321

Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom.

Kraków, 31.03.2014

Signed on behalf of the Manufacturer

Justyna Wiśniowska-Woźny

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Technical Documentation Specialist

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REGON: 350967107

Registered in Poland: KRS 36244

Sąd Rejonowy dla Krakowa-Śródmieścia

XI Wydział Gospodarczy KRS

Paid-up capital: 8 643 400 PLN

ISO certificates (DNV CERTIFIED):

ISO 9001:2008;

no. 93133-2011-AQ-POL-FINAS

ISO 13485:2003;

no. 93134-2011-AQ-POL-FINAS

www.mercatormedical.eu

