

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 non-sterile examination gloves:

Type	Brand	Size
nitrile, powder free, blue / violet colour	nitrylex® PF PROTECT	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

meet the essential requirements of the **Council Directive 93/42/EEC** amended by the Directive 2007/47/EC and European harmonized standards: EN 455, EN 980, EN 1041.

Conformity assessment procedure of the medical device according to : Annex I and Annex VII of the Council Directive 93/42/EEC.

The gloves, described above, classified as **Personal Protective Equipment, Category I – for minimal risk** are in conformity with the provisions of the **Council Directive 89/686/EEC** and European harmonized standards: EN 420, EN 374-1, EN 374-2.

Kraków, 29.05.2015

Sign on behalf of the Manufacturer:

Justyna Wiśniowska-Woźny

Justyna Wiśniowska-Woźny
Product Specialist

MERCATOR MEDICAL
Spółka Akcyjna
ul. Heleny Modrzejewskiej 30
31-327 Kraków
tel. +48 12 66 55 400, fax +48 12 66 55 415
-6-

Registered Office
ul. H. Modrzejewskiej 30
31-327 Kraków, Poland
ph./fax: +48 (12) 66 55 400
fax: +48 (12) 66 55 415
medical@mercatormedical.eu

Logistics Center
Stary Brześć 25E
87-880 Brześć Kujawski, Poland
ph./fax: +48 (54) 252 10 20
fax: +48 (12) 252 10 21
kujawy@mercatormedical.eu

VAT NO.: PL 677 10 36 424
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



EC DECLARATION OF CONFORMITY

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

declares under sole responsibility that non-sterile examination gloves:

Type	Brand	Sizes
latex, powder free	comfort® PF	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

meet the essential requirements of the **Council Directive 93/42/EEC** amended by the Directive 2007/47/EC and European harmonized standards: EN 455, EN 980, EN 1041.

Conformity assessment procedure of the medical device according to : Annex I and Annex VII of the Council Directive 93/42/EEC.

The gloves, described above, classified as **Personal Protective Equipment, Category III** are in conformity with the provisions of the **Council Directive 89/686/EEC** and European harmonized standards:



The gloves, described above, are identical to the Personal Protective Equipment which was subject to the EC Type Examination Certificate Number 04813597 issued by:

CENTEXBEL, Notified Body 0493

Technologie Park 7, BE-9052 Zwijnaarde (Gent)

and are subject to the procedure set out in Article 11B of the Council Directive 89/686/EEC under the supervision of:

SGS United Kingdom Limited, Notified Body 0120

Unit 202B, Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom.

Kraków, 29.05.2015

MERCATOR MEDICAL
Spółka Akcyjna
ul. Heleny Modrzejewskiej 30
31-327 Kraków
tel. +48 12 66 55 400, fax +48 12 66 55 415

Signed on behalf of the Manufacturer:

Justyna Wiśniowska-Woźny
Justyna Wiśniowska-Woźny
Product Specialist

Registered Office
ul. H. Modrzejewskiej 30
31-327 Kraków, Poland
ph./fax: +48 (12) 66 55 400
fax: +48 (12) 66 55 415
medical@mercatormedical.eu

Logistics Center
Stary Brześć 25E
87-880 Brześć Kujawski, Poland
ph./fax: +48 (54) 252 10 20
fax: +48 (12) 252 10 21
kujawy@mercatormedical.eu

VAT NO.: PL 677 10 36 424
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

