

MANUFACTURER

SORIMEX spółka z ograniczoną odpowiedzialnością spółka komandytowa
ul. Równinna 25, 87-100 Toruń, Poland

WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT:

MEDICAL DEVICE:

Nitrile examination powder free gloves

MODELS:

MASTER GLOVE NITRILE Standard Black +
MASTER GLOVE NITRILE Standard Blue +

CLASS:

- I rule I according to Annex IX of 93/42/EEC Directive
- meets all provisions of Directive 93/42/EEC which apply to it.

- Conformity assessment procedure:
- Annex VII of 93/42/EEC directive (chapter 5 and 6 of Annex VII are not applicable).

APPLIED HARMONIZED STANDARDS, NATIONAL STANDARDS OR OTHER NORMATIVE DOCUMENTS:

- EN ISO 13485:2016
- EN ISO 14971:2012
- EN 1041:2008 + A1:2013
- EN ISO 15223-1:2016
- EN ISO 10993-1:2009
- EN 455-1:2000
- EN 455-2:2015
- EN 455-3:2015
- EN 455-4:2009

Batch numbers of the products covered by this declaration can be found on the Quality Control Certificate confirming the release of product for sale and should be treated as part of this declaration.



Mariusz Sobociński

Prezes Zarządu

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Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

CERTIFICATE NUMBER:

2777/11578-02/E12-01

NOTIFIED BODY:

SATRA TECHNOLOGY: 2777

APPLIED HARMONIZED STANDARDS, NATIONAL STANDARDS OR OTHER NORMATIVE DOCUMENTS:

- EN 420:2003+A1:2009
- EN ISO 374-1:2016+A1:2018
- EN ISO 374-5:2016

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