

### 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, textured

### MODELS:

MASTER GLOVE nitrile Standard Black+  
MASTER GLOVE nitrile Standard Blue+

### CLASS:

I according to rule 1 and 5 of Annex VIII of the Regulation of the European Parliament and of the Council (EU) 2017/745  
- product conformity assessment was carried out in accordance with Annex II, Annex III of the Regulation of the European Parliament and of the Council (EU) 2017/745

### 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

### PPE CATEGORY:

after EU-type examination, it has been shown that this product group meets the applicable essential health and safety requirements set out in Annex II to the PPE Regulation (EU) 2016/425 as a category III product.

### CERTIFICATE NUMBER:

2777/11578-02/E12-01

### NOTIFIED BODY:

SATRA TECHNOLOGY EUROPE Ltd: Number: 2777  
Bracetown Business Park. Clonee. D15YN2P. Ireland



Mariusz Sobociński

Prezes Zarządu

### APPLIED STANDARDS:

- EN 420:2003+A1:2009
- EN ISO 374-1:2016+A1:2018
- EN 374-4:2013
- EN ISO 374-5:2016



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