

MANUFACTURER

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

WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT:

BASIC UDI-DI:

5903002221185P

MEDICAL DEVICE:

Nitrile examination powder free gloves, textured

MODELS:

MASTER GLOVE nitrile PF simple

CLASS:

I according to rule 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 ISO13485:2016/AC:2018
- EN ISO 14971:2012
- EN 1041:2008 + A1:2013
- EN ISO 15223-1:2016
- EN ISO 16523-1:2015
- 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.

CERFITICTE NUMBER:

2777/10648-04/E20-01

NOTIFIED BODY:

SATRA TECHNOLOGY EUROPE Ltd: Numer: 2777
Bracetown Business Park, Clonee, D15YN2P, Irlandia



Ewa Sobocińska

Wiceprezes Zarządu

APPLIED STANDARDS:

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

