

### MANUFACTURER

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

### WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT:

#### MEDICAL DEVICE:

Latex examination gloves

#### MODELS:

Powdered: MASTER GLOVE latex classic, MASTER GLOVE latex classic texture, MASTER GLOVE latex classic blue, MASTER GLOVE latex classic mint, MASTER GLOVE latex simple

Powder Free: MASTER GLOVE latex PF chlori, MASTER GLOVE latex PF poly

#### 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
- ISO 11193-1:2008

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