

Declaration of Conformity

Powdered Latex Examination Gloves

Definition:

EN 455 part 1, 2, 3 & 4

Essential Requirements MDD 93/42/EEC

Quality system of the manufacturer: ISO 9001: FM 512209 and ISO 13485 & EN ISO 13485: MD 512207

Declaration of conformity:

With this Declaration of conformity, we declare that the abovementioned product conforms to the requirements laid down in MDD 93/42/EEC.

1. Manufacturer:

Medipart ApS
Jernbanegade 75-77
DK- 5500 Middelfart
Denmark

2. Identification:

E2SP - Specification Examination Gloves Powdered Latex.
Brand: Cosaline

3. European Standards:

EN 455 part 1, 2, 3 & 4

4. Normative References:

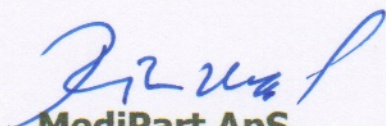
Following the provision in conformity assessment procedure listed in Annex VII of Medical Device Directive 93/42/EEC, as amended by the Council directive 2007/47/EC

5. Category:

Class I.

6. Date:

February 10, 2020



MediPart ApS

Rikke Nygaard