

Declaration of Conformity

Nitrile Examination Gloves Ultra Protect – Non sterile 240mm and 290mm – Blue & White

Definition:

EN 455 part 1, 2, 3 & 4

Essential Requirements MDD 93/42/EEC as amended by the Council directive 2007/47/EC.

Quality System of the manufacturer ISO 9001:2008, Ref.: 12 100 25208 TMS, ISO 13485:2003 Ref.: QS1 14 01 55298 014, EN ISO 13485:2012+AC:2012 Ref.: Q1N 13 10 55298 013, ISO 14001:2004 Ref.: TUV104 13 2768/2 and OHSAS 18001:2007 - TUV116 13 2768/2

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 as amended by the Council directive 2007/47/EC.

1. Manufacturer:

MediPart ApS
Naffet 2a
6100 Haderslev
Denmark

2. Identification:

E3UP - Specification Nitrile Examination Gloves Ultra Protect Powder Free - Non Sterile.

3. European Standards:

EN 455 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:

20th November 2018


Rikke Nygaard