

Declaration of Conformity

Vinyl Examination Gloves – Non sterile 240 mm – Clear 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: ISO 9001:2015, TUV USA Ref: QS5 062837 0013 Rev.00 and EN ISO 13485:2016, TUV Germany Ref: Q5 18 04 62837 012.

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. Supplier:

MediPart ApS
Naffet 2a
6100 Haderslev
Denmark

2. Identification:

E4SF - Specification Vinyl Examination Gloves – 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:

29th July 2019


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