



EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC concerning medical devices

We,

ARISTA LATINDO IND. LTD. PT.
JL. K.H. MOH. MANSYUR #128
JAKARTA 11210, INDONESIA

declare under our sole responsibility that the following non-sterile products under Class I meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them:

1. Powdered Latex Examination Gloves, Smooth
2. Powdered Latex Examination Gloves, Textured
3. Powdered Latex Examination Gloves, Textured (Blue color)
4. Powder Free Latex Examination Gloves, Smooth
5. Powder Free Latex Examination Gloves, Textured
6. Powder Free Latex Examination Gloves, Finger Textured
7. Blue Latex Safety Gloves, Powdered (Medical Purpose)
8. Blue Latex Safety Gloves, Powder Free (Medical Purpose)
9. Lightly Powdered Vinyl Examination Gloves (Clear color)
10. Lightly Powdered Vinyl Examination Gloves (Blue color)
11. Lightly Powdered Vinyl Examination Gloves (Cream color)
12. Lightly Powdered Vinyl Examination Gloves (Violet color)
13. Lightly Powdered Vinyl Examination Gloves (Pink color)
14. Powder Free Vinyl Examination (Clear color)
15. Powder Free Vinyl Examination (Blue color)
16. Powder Free Vinyl Examination (Cream color)
17. Powder Free Vinyl Examination (Violet color)
18. Powder Free Vinyl Examination (Green color)
19. Powder Free Vinyl Examination (Pink color)
20. Powder Free Vinyl Examination (Vitamin E)
21. Powder Free Nitrile Examination Gloves (White color)
22. Powder Free Nitrile Examination Gloves (Blue color)
23. Powder Free Nitrile Examination Gloves (Purple color)
24. Powdered Nitrile Examination Gloves (Blue color)
25. Pre-Powdered Medical Latex Examination Gloves
26. Pre-Powdered Latex Examination Gloves
27. Pre-Powdered Medical Latex Examination Gloves

The products above are intended to be used as: Disposal Examination Gloves, Class I device.





ARISTA LATINDO INDUSTRIAL LTD. P.T
GLOVE MANUFACTURER

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Conformity assessment was performed according to Article II (5), Annex VII Section 3.

The following standards were used to prove the products conformity with the essential requirements of the above directive:

- ◆ EN455 Part 1
- ◆ EN455 Part 2
- ◆ EN455 Part 3

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

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Linga Sumarta
QA Manager
Jakarta 13 February 2007

