

Chlorinated PowderFree Nitrile Examination Gloves **TF 005**

Attachment 2

DECLARATION OF CONFORMITY

Plant of Manufacture:

COMFORT RUBBER GLOVES INDUSTRIES SDN BHD

Lot 821 & 2209, Jalan Matang,

34750 Matang, Perak,

Malaysia.

Lot 1874, Jalan Kampung Dew,

Simpang Halt, 34700 Simpang, Taiping, Perak, Malaysia.

Contact Person

Telephone Number

Mr. Ng Kok Howe 605-847 2777 / 2888

Facsimile No.

605-847 9108 / 6250

Position

QA & QMS Manager

(Quality Management Representative)

E-mail

garyng@comfort-rubber.com.my

Competent Authority

Certificate No.

SGS United Kingdom Ltd Systems & Services Certification

MY09/77229

Product

Chlorinated PowderFree Nitrile Examination Gloves

Classification

Class 1

Conformity Assessment Route

Rule 1

Intended Use

It is a disposable device intended for medical purpose that is worn on the

examiner's hands to prevent contamination between patient and

examiner.

Hereby declare that product described as Chlorinated PowderFree Nitrile Examination Gloves is in conformity with the provision of Regulation (EU) 2017/745 of The European Parliament and of The Council (Non-Invasive Devices - Rule 1). Where such is the case, with the national standard transposing harmonized standard Nos. EN 455-1, EN 455-2, EN 455-3 and EN 455-4.

Signed

Name Position

Ng Kok Howe QA Manager

Date

25 October 2019