

DECLARATION OF CONFORMITY

We, Rimba Glove Sdn. Bhd, hereby declare under our sole responsibility that the medical device described hereafter:-

Product description: Powder Free Nitrile Examination Gloves - Non Sterile.

Commercial Brands: Rimba Glove.

Product Class I.

Under classification (MDD 93/42/EEC, Annex IX, Rule 5); has met the provisions of the Medical Directive 93/42/EEC (as amended by Directive 2007/47/EC), and harmonized standards as follows:-

EN ISO 13485- Quality Management Systems.

EN 455-1- Medical gloves for single use: Requirements and testing for freedom from holes.

EN 455-2- Medical gloves for single use: Requirements and testing for physical properties.

EN 455-3- Medical gloves for single use: Requirements and testing for biological evaluation.

EN 455-4-Medical gloves for single use: Requirements and testing for shelf life determination

Rimba Glove Sdn. Bhd. Performs Quality Analysis or Pre-Shipment Reports for clarity and testing of EN 455. This declaration is supported by Quality Management System certification based on the harmonized standard ISO 13485:2016, Certified by SGS - Certification No.MY21/1811030645

European Authorized Representative: Jumapanilo S.L.

Address: C/Mateo Carrion Arranz 14, Almendralejo, 06200 Badajoz, Spain.

Done at;

Date: 25 May 2021

Rimba Glove SDN BHD.

Address: Plot 37, Medan Tasek, Tasek Industrial Area, 31400 Ipoh, Perak, Malaysia.

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Name: Cheah Eujon

Position: Director.

Certificates, declarations and supporting documents are retained on our premises at all times.