



EC DECLARATION OF CONFORMITY

With regard to MDD 93/42/EEC as amended by 2007/47/EC for Medical Devices

Name of the Company : **GIS RESOURCES SDN BHD**
Address : A-11-6, PLAZA TARAGON KELANA, JALAN BAHAGIA,SS6,
47301 PETALING JAYA, SELANGOR, MALAYSIA.

Product Name : **Examination Gloves - Nitrile**
Classification and Justification : As per annexure IX of MDD 93/42/EEC, as amended by
2007/47/EC section 1.1 Rule 1 it's a Class I Medical Device. All
non-invasive devices are in Class I.

Brand Names : **PRINCE PREMIUM +**

Authorized Representative Name : **Europecert**
and Address : Alstr. 97, 41063 Mönchengladbach, Germany
support@europecert.eu



We hereby under our sole responsibility declare, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the essential requirements of 93/42/EEC.

This declaration of conformity is issued under the sole responsibility of GIS RESOURCES SDN BHD, . We hereby declare that the medical device specified above meet the provision of the Annex VII of MDD 93/42/EEC as amended by 2007/47/EC for medical devices.

This declaration is based on

- a) EN ISO 15223-1: 2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 14971:2012, EN ISO 13485:2016
- b) Technical File ID with issue date: GIS-TF-002, 10.02.2020

Manufacturer : GIS RESOURCES SDN BHD
Name & Designation : SENTHIL RAJ RAMACHANDERA & DIRECTOR

Signature :  

Date : 14.09.2020
Place of Issue : PETALING JAYA, SELANGOR, MALAYSIA.