DECLARATION OF CONFORMITY

We ECO MEDI GLOVE SDN. BHD (hereinafter referred to as "EMG") was incorporated on year 2014 and previous was under name of Sentimed Sdn. Bhd. Specialized manufacturing of Non-Sterile Powder Free Nitrile Examination Gloves in Malaysia. The company is located in

Plant 2: Lot 23836, Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
Kamunting, Perak
Malaysia.

declare under our sole responsibility that the medical device described hereafter:

3Mil Low Extractable Nitrile Protective Gloves
Brand: EMG
Size: XS, S, M, L, XL, XXL

under Classification (MDR, Annex IX): **Category 3**

has meet the provisions of the MDR 93/42/EEC (as amended by Regulation 2007/47/EC), Guidance on the application of council regulation (EU) 2016/425 and relevant harmonized standards as follows: -

EN ISO 13485:2012	**Medical Devices- Quality management systems - Requirements for regulatory purposes**
ISO 14971:2012	**Medical devices- Application of risk management to medical devices**
ISO 10993-10:2010	**Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity**
ISO 15223-1:2012	**Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements**
89/686/EEC	**Guidance on the application of council directive**
EN374-2	**Determination of resistance of water leak and air leak.**
EN 455-1:2000	**Requirements and Testing for Freedom from Holes**
EN 455-2:2009 + A2 2013	**Requirements and Testing for Physical Properties**
EN 455-3:2006	**Medical Gloves for Single Use – Part 3 : Requirements and Testing for Biological Evaluation**
ASTM D5151-15	**Standard Test Method for Detection of Holes in Medical Gloves**
ASTM D5712-15	**Standard Test Method for Analysis of Protein in Natural Rubber and its Products using the Modified Lowry Method**
ASTM D412-15	**Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers – Tension**
EN374-3	**Permeation of liquid chemical through a protective clothing material**
EN388-6.1	**Determination of the abrasion resistance on Martindale with emery paper**
EN388-6.2	**Determination of blade cut resistance**
EN388-6.3	**Determination of tearing resistance-glove**
EN388-6.4	**Determination of the puncture resistance**
EN 14362-1	**Arylamines coming from prohibited azo dyes in textiles**

Following the provisions in conformity assessment procedure listed in Annex II and VII of Medical Device Regulation 93/42/EEC (as amended by Regulation 2007/47/EC). This declaration is supported by the Quality System certification based on the harmonized standard **ISO 13485:2003**, Quality System Certificate with reference number **49711** with the certification are issue on 14th May 2015 and delivered by accreditation body with the certification No 015 held by NQA with the registered office at 20-22 Beadford Row,London,WCIR 4JS

The European Authorised Representative, Obelis S.A. is located at Boulevard Général Wahis 53, 1030 Brussels, Belgium.

Notify Body: SGS (0120)
Address: Unit 202B Worle Parkway,
Weston-Super-Mare,
BS22 6WA UK

All supporting documentations are retained at the premises of the manufacturer.

Executive Director (ED)

Date: 26th December 2018

ECO MEDI GLOVE SDN. BHD.

Revision History

Revision No.	Revision Date	DCN No.	Description of Revision	Revised By
00	26/12/2018	-	New Document	Suresh Kumar