

**CERTIFICATE OF CONFORMITY**

We herewith declare that the following product meet the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC and all supporting documentation is retained at the premise of the manufacturer.

EC Certificate(s)	<b>G1 11 10 61155 005</b>
Manufacturer Address	<b>TERANG NUSA SDN. BHD. 1, Jalan 8, Pengkalan Chepa 2, Industrial Zone, 16100 Kota Bharu, Kelantan, MALAYSIA</b>
European Representative	<b>EMERSON &amp; CO. S.R.L. Piazza Della Vittoria 10/12 16121 Genova ITALY Tel : 0039-010-543 463 Fax: 0039-010-565 480</b>
Brand	<b>FUSIONE</b>
Product Description	<b>Sterile Synthetic Surgical Gloves Powderfree</b>
Classification (MDD 93/42, Annex IX):	<b>IIa (Rule 7)</b>
Conformity Assessment	<b>Annex II excluding 4</b>
Standards	<b>ISO 15223-1:2012, EN 455-1:2000, EN 455-2:2009+A2:2013 and EN 455-3:2006 ISO 14971:2009, ISO 10993-1:2009, ISO 10282:2002, ISO 11607-1:2006 and ISO 11137-1:2006</b>
Notified Body	<b>TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany (CE 0123)</b>

Kota Bharu, Malaysia, 14<sup>th</sup> July 2014

  
Rahayu MZ  
Management Representative

**TERANG NUSA Sdn. Bhd. (164501-X)**

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