TERANG NUSA

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)	**G1 11 10 61155 005**
Manufacturer Address	**TERANG NUSA SDN. BHD. 1, Jalan 8, Pengkalan Chepa 2, Industrial Zone, 16100 Kota Bharu, Kelantan, MALAYSIA**
European Representative	**EMERSON & CO. S.R.L. Piazza Della Vittoria 10/12 16121 Genova ITALY Tel : 0039-010-543 463 Fax: 0039-010-565 480**
Brand	**SENSIFLEX PLUS**
Product Description	**Sterile Latex Surgical Transparent Powderfree**
Classification (MDD 93/42, Annex IX):	**IIa (Rule 7)**
Conformity Assessment	**Annex II excluding 4**
Standards	**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**
Notified Body	**TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany (CE 0123)**

Kota Bharu, Malaysia, 14th July 2014

Rahayu MZ
Management Representative