

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	MAXITEX <i>low level</i>
Product Description	Sterile Latex Surgical Gloves Prepowdered
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

TERANG NUSA Sdn. Bhd. (164501-X)

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