



Product Service

# EC - CERTIFICATE

## Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 07 06 51097 012

**Manufacturer:** Unomedical Snd. Bhd.

Bakar Arang Industrial Estate  
08000 Sungai Petani, Kedah  
MALAYSIA

**EC-Representative:** Unomedical A/S

Kongevejen 2  
3460 Birkerød  
DENMARK

**Product  
Category(ies):**

**Latex & Silicone Urological Foley Catheters  
Latex & Silicone Urological Foley Catheters  
with pre-filled Syringes  
PVC & Silicone Endotracheal Tubes  
PVC & Silicone Tracheostomy Tubes  
Intubating Stylets  
Laryngeal Airway**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

**Report No.:** QMC-0207-004

**Valid until:** 2010-12-06

**Date,** 2007-06-27

Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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**Facility(ies):**

Unomedical Snd. Bhd.  
Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah,  
MALAYSIA