



Product Service

# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2 04 11 12772 003

**Manufacturer:** **Vygon GmbH & Co. KG**  
Prager Ring 100  
52070 Aachen  
GERMANY

**Facility(ies):** Vygon GmbH & Co. KG  
Prager Ring 100, 52070 Aachen, GERMANY

**Product Category(ies):** **Catheters and catheter sets for cardiology**

The Certification Body of TÜV Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective products / product categories according to Annex V, 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 IIb and III products an additional Annex III - certificate is mandatory. See also notes overleaf.

**Report No.:** 70083041

**Valid until:** 2009-12-31

**Date,** 2004-12-31



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

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