



Product Service

# EC Design Examination Certificate

(Annex II, section 4 of the Directive 93/42/EEC on Medical Devices)

No. G7 10 08 55474 008

**Manufacturer:** Omega Critical Care Ltd.  
Omega House, 2 Cairn Court, Nerston West  
East Kilbride  
G74 4NB  
UNITED KINGDOM

**Product:** Catheters for single use  
Continuous Cardiac Output Pulmonary  
Artery Catheter

**Model(s):** Model name Model No.  
truCATH.ip TCH-5100

**Parameters:** --

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the aforementioned devices according to Annex II, section 4 of the Directive 93/42/EEC on Medical Devices. The design of the devices conforms to the provisions of this Directive. For marketing of these products an additional Annex II.3 certificate is mandatory. See also notes overleaf.

**Report no.:** 75910659

**Valid until:** 2015-09-04

**Date,** 2010-10-01

Hans-Heiner Junker



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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