



Product Service

EC-CERTIFICATE

Full Quality Assurance System

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

No. G1 10 08 55474 007

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

Facility(ies): Omega Critical Care Ltd.
 Omega House, 2 Cairn Court, Nerston West, East Kilbride, G74 4NB, UNITED KINGDOM

Product Category(ies): **Continuous cardiac output monitoring systems: continuous cardiac output monitoring catheter and continuous cardiac output monitoring unit**

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.

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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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