



America

# EC - CERTIFICATE

## Full Quality Assurance System

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

No. G1 06 02 45171 004

**Manufacturer:** **Biosafe S. A.**  
 Route du Petit-Eysins  
 1262 Eysins  
 SWITZERLAND

**Facility(ies):** Biosafe S. A.  
 Route du Petit-Eysins, 1262 Eysins, SWITZERLAND

**Product Category(ies):** **Separation devices, including their tubing sets and transfusion accessories for blood, blood derivatives and cellular products**

The Certification Body of TÜV 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.:** 70112735

**Valid until:** 2008-05-26



**Date,** 2006-02-16

*Reiner Krumme*  
 Reiner Krumme

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

Page 1 of 1