

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60094048 0001

**Report No.:** 21197341 003

**Manufacturer:** MediPac GmbH  
Eduard-Rhein-Str. 1-3  
53639 Königswinter  
Deutschland

**Products:** Sterile single use devices for self-blood-therapy and  
catheter blocking  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60026401 0001

**Expiry Date:** 2019-11-18

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2014-11-19

**Date:** 2014-11-19

Notified Body

  
Dr. K. Kluge



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60094048 0001  
**Report No.:** 21197341 003

**Manufacturer:** MediPac GmbH  
Eduard-Rhein-Str. 1-3  
53639 Königswinter  
Deutschland

**Products:**

**Vacuum bottles**

- Vacuum bottles 250 ml
- Vacuum bottles 500 ml
- Vacuum bottles 250 ml  
containing 12 ml Sodium Citrate solution 3.13%
- Vacuum bottles micro perl 250 ml  
containing 12 ml Sodium Citrate solution 3.13%

**Sodium Citrate solution 3,13%**

- Ampules 10 ml
- Injection bottles 100 ml

**Transfer filter sets**

**Transfusion sets**

**Heidelberger extensions**

**Blood taking sets**

**Date:** 2014-11-19

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**

