TÜVRheinland®

EC Certificate

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

Registration No.: HD 60131322 0001

Report No.: 21197341 017

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

Products:
Sterile single use devices for self-blood-therapy and catheter locking

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60094048 0001

Expiry Date: 2024-05-26

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: 2019-11-05

Date: 2019-11-05

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Dr. T. Kießling

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131322 0001
Report No.: 21197341 017

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

Products included:

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dr. T. Kießling

Date: 2019-11-05