



Certificate

EC-Certificate

(Production quality assurance system)

according to annex V of Medical Devices Directive 93/42/EEC

It is herewith confirmed by

BSI Group Deutschland GmbH

Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main
Germany

in its function as Notified Body (0535), that the manufacturer:

BİMED TEKNİK ALETLER SANAYİ VE TİCARET A.Ş.

Beylikdüzü Mevkii, S.S. Bakır ve
Pirinç Sanayi Sitesi Leylak
Caddesi No:15
TR-34520 Büyükçekmece –
ISTANBUL Turkey

concerning the medical device

**sterile syringes and vaginal specula,
dosage syringes, dosage pipette,
measuring cup, measuring spoon**

fulfills the requirements according to Annex V of the Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the production and final inspection of the specified devices.

For the placing on the market of class III products an Annex III certificate is required.

The appendix is part of this certificate and contains 2 pages.

Report No.: SMO7926098

Certificate No.: CE 574552



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-248.10.04

First Issue Date:
April 19, 2007

Based on periodical surveillance
this certificate is valid until
April 18, 2017.

Current Issue Date: December 19, 2014

E. Schwöder
Certification Body



Appendix of EC-Certificate

(Production quality assurance system)

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Medical devices of the manufacturer:

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Pirinç Sanayi Sitesi Leylak

Caddesi No:15

TR-34520 Büyükçekmece –

ISTANBUL Turkey

| Name of product | UMDNS | class |
|---|--------|-------|
| 3 parts – 50 ml KATHETER – without needle | 13-936 | Is* |
| 2 parts – 50 ml KATHETER – without needle | 13-936 | Is* |
| 2 parts – 30 ml KATHETER – without needle | 13-936 | Is* |
| 2 parts – 50 ml LUER-LOCK without needle | 15-256 | Is* |
| 2 parts – 50 ml LUER without needle | 15-256 | Is* |
| 2 parts – 30 ml LUER without needle | 15-256 | Is* |
| 2 parts – 30 ml LUER-LOCK without needle | 15-256 | Is* |
| 3 parts – 50 ml LUER with needle | 15-256 | IIa |
| 3 parts – 50 ml LUER without needle | 15-256 | Is* |
| 3 parts – 50 ml LUER-LOCK with needle | 15-256 | IIa |
| 3 parts – 50 ml LUER-LOCK without needle | 15-256 | Is* |
| VAGINAL SPECULUM MEDIUM | 13-666 | Is* |
| VAGINAL SPECULUM SMALL | 13-666 | Is* |
| VAGINAL SPECULUM LARGE | 13-666 | Is* |
| DOSAGE SYRINGES | 16-325 | Im* |
| DOSAGE PIPETTE | 16-325 | Im* |
| MEASURING CUP | 16-325 | Im* |
| MEASURING SPOON | 16-325 | Im* |

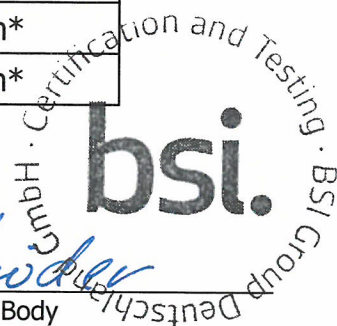


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Caddesi No:15

TR-34520 Büyükçekmece –

ISTANBUL Turkey

| Name of product | UMDNS | class |
|---|--------|-------|
| 3 parts – 50 ml LUER FLATSEAL without needle | 15-256 | Is* |
| 3 parts – 50 ml LUER LOCK FLATSEAL without needle | 15-256 | Is* |
| 3 parts – 50 ml KATHETER FLATSEAL without needle | 13-936 | Is* |
| 3 parts – 30 ml LUER FLATSEAL without needle | 15-256 | Is* |
| 3 parts – 30 ml LUER LOCK FLATSEAL without needle | 15-256 | Is* |
| 3 parts – 30 ml KATHETER FLATSEAL without needle | 13-936 | Is* |
| 3 parts – 30 ml KATHETER without needle | 13-936 | Is* |
| 3 parts – 30 ml LUER without needle | 15-256 | Is* |
| 3 parts – 30 ml LUER LOCK without needle | 15-256 | Is* |
| 3 dose injection syringes with needle | 15-256 | IIa |

* With Class I products placed on the market in sterile condition and Class I devices with a measuring function application of the above mentioned Annex and the intervention by the notified body is limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.



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