



# E C C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

M.2018.106.9142-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Mah. Sağlık Sok. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY

Manufacturing and Storage : Malıköy Başkent OSB Mah. 4. Cadde No: 17 Sincan ANKARA / TURKEY

Storage 2 : 29 Ekim Mah. Necip Fazıl Bulv. No:71 Yenikent Sincan ANKARA / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II  
(Excluding Section 4)

Product : Single Use, Sterile, Absorbable Haemostat Oxidized Regenerated  
Cellulose (ORC) - Class III  
Single Use, Sterile, Absorbable Haemostat Oxidized  
Cellulose (OC) - Class III

GMDN : 38771

Product Types are attached.

Certificate Number : M.2018.106.9142

Report Number : MD.3532.IB

Initial Assessment Date : 07.11.2017

Registration Date : 02.01.2018

Revision Date /No : 05.02.2018/01

Expiry Date : 01.01.2023

UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM 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 audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).

CE  
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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9142 and with the registration date of 02.01.2018 and with the revision date of 05.02.2018 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices

| ABSORBABLE HAEMOSTAT, OXIDIZED REGENERATED CELLULOSE (ORC) CLASS III |              |                 |              |              |                 |
|----------------------------------------------------------------------|--------------|-----------------|--------------|--------------|-----------------|
| PRODUCT CODE                                                         | PRODUCT CODE | PRODUCT SIZE    | PRODUCT CODE | PRODUCT CODE | PRODUCT SIZE    |
| RX0502                                                               | RX0502*      | 1,25cm x 5cm    | BR0502       | BR0502*      | 1,25cm x 5cm    |
| RX0502X                                                              | RX0502X*     | 1,25cm x 5cm    | BR0502X      | BR0502X*     | 1,25cm x 5cm    |
| RX1001                                                               | RX1001*      | 2,5cm x 2,5cm   | BR1001       | BR1001*      | 2,5cm x 2,5cm   |
| RX1001X                                                              | RX1001X*     | 2,5cm x 2,5cm   | BR1001X      | BR1001X*     | 2,5cm x 2,5cm   |
| RX1002                                                               | RX1002*      | 2,5cm x 5cm     | BR1002       | BR1002*      | 2,5cm x 5cm     |
| RX1002X                                                              | RX1002X*     | 2,5cm x 5cm     | BR1002X      | BR1002X*     | 2,5cm x 5cm     |
| RX1003                                                               | RX1003*      | 2,5cm x 7,5cm   | BR2003       | BR2003*      | 5cm x 7,5cm     |
| RX1063                                                               | RX1063*      | 2,5cm x 9cm     | BR2003X      | BR2003X*     | 5cm x 7,5cm     |
| RX2003                                                               | RX2003*      | 5cm x 7,5cm     | BR2004       | BR2004*      | 5cm x 10cm      |
| RX2003X                                                              | RX2003X*     | 5cm x 7,5cm     | BR2004X      | BR2004X*     | 5cm x 10cm      |
| RX2004                                                               | RX2004*      | 5cm x 10cm      | BR2014       | BR2014*      | 5cm x 35cm      |
| RX2004X                                                              | RX2004X*     | 5cm x 10cm      | BR2014X      | BR2014X*     | 5cm x 35cm      |
| RX2014                                                               | RX2014*      | 5cm x 35cm      | BR3004       | BR3004*      | 7,5cm x 10cm    |
| RX2014X                                                              | RX2014X*     | 5cm x 35cm      | BR3004X      | BR3004X*     | 7,5cm x 10cm    |
| RX3004                                                               | RX3004*      | 7,5cm x 10cm    | BR4004       | BR4004*      | 10cm x 10cm     |
| RX3004X                                                              | RX3004X*     | 7,5cm x 10cm    | BR4004X      | BR4004X*     | 10cm x 10cm     |
| RX4004                                                               | RX4004*      | 10cm x 10cm     | BR4008       | BR4008*      | 10cm x 20cm     |
| RX4004X                                                              | RX4004X*     | 10cm x 10cm     | BR4008X      | BR4008X*     | 10cm x 20cm     |
| RX4008                                                               | RX4008*      | 10cm x 20cm     | BR6009       | BR6009*      | 15cm x 23cm     |
| RX4008X                                                              | RX4008X*     | 10cm x 20cm     | BR6009X      | BR6009X*     | 15cm x 23cm     |
| RX6009                                                               | RX6009*      | 15cm x 23cm     | BK1001       | BK1001*      | 2,6cm x 2,6cm   |
| RX6009X                                                              | RX6009X*     | 15cm x 23cm     | BK1001X      | BK1001X*     | 2,6cm x 2,6cm   |
| RK1001                                                               | RK1001*      | 2,6cm x 2,6cm   | BK1003       | BK1003*      | 2,6cm x 10cm    |
| RK1001X                                                              | RK1001X*     | 2,6cm x 2,6cm   | BK1003X      | BK1003X*     | 2,6cm x 10cm    |
| RK1003                                                               | RK1003*      | 2,6cm x 10cm    | BK2003       | BK2003*      | 5cm x 7,5cm     |
| RK1003X                                                              | RK1003X*     | 2,6cm x 10cm    | BK2003X      | BK2003X*     | 5cm x 7,5cm     |
| RK2003                                                               | RK2003*      | 5cm x 7,5cm     | BK3004       | BK3004*      | 7,6cm x 10,2cm  |
| RK2003X                                                              | RK2003X*     | 5cm x 7,5cm     | BK3004X      | BK3004X*     | 7,6cm x 10,2cm  |
| RK3004                                                               | RK3004*      | 7,6cm x 10,2cm  | BK6009X      | BK6009X*     | 15,2cm x 23cm   |
| RK3004X                                                              | RK3004X*     | 7,6cm x 10,2cm  | BF1002X      | BF1002X*     | 2,6cm x 5,1cm   |
| RK6009                                                               | RK6009*      | 15,2cm x 23cm   | BF2003X      | BF2003X*     | 5cm x 7,5cm     |
| RF1002                                                               | RF1002*      | 2,6cm x 5,1cm   | BF2004X      | BF2004X*     | 5,1cm x 10,2cm  |
| RF2003                                                               | RF2003*      | 5cm x 7,5cm     | BF2007X      | BF2007X*     | 5cm x 10cm      |
| RF2004                                                               | RF2004*      | 5,1cm x 10,2cm  | BF3003X      | BF3003X*     | 7,5cm x 7,5cm   |
| RF3003                                                               | RF3003*      | 7,5cm x 7,5cm   | BF4004X      | BF4004X*     | 10,2cm x 10,2cm |
| RF4004                                                               | RF4004*      | 10,2cm x 10,2cm |              |              |                 |
| ABSORBABLE HAEMOSTAT, OXIDIZED CELLULOSE (OC) CLASS III              |              |                 |              |              |                 |
| PRODUCT CODE                                                         | PRODUCT CODE | PRODUCT SIZE    | PRODUCT CODE | PRODUCT CODE | PRODUCT SIZE    |
| ZC0502                                                               | ZC0502*      | 1,25cm x 5cm    | ZC2014       | ZC2014*      | 5cm x 35cm      |
| ZC0502X                                                              | ZC0502X*     | 1,25cm x 5cm    | ZC2014X      | ZC2014X*     | 5cm x 35cm      |
| ZC1001                                                               | ZC1001*      | 2,5cm x 2,5cm   | ZC3004       | ZC3004*      | 7,5cm x 10cm    |
| ZC1001X                                                              | ZC1001X*     | 2,5cm x 2,5cm   | ZC3004X      | ZC3004X*     | 7,5cm x 10cm    |
| ZC1002                                                               | ZC1002*      | 2,5cm x 5cm     | ZC4004       | ZC4004*      | 10cm x 10cm     |
| ZC1002X                                                              | ZC1002X*     | 2,5cm x 5cm     | ZC4004X      | ZC4004X*     | 10cm x 10cm     |
| ZC2003                                                               | ZC2003*      | 5cm x 7,5cm     | ZC4008       | ZC4008*      | 10cm x 20cm     |
| ZC2003X                                                              | ZC2003X*     | 5cm x 7,5cm     | ZC4008X      | ZC4008X*     | 10cm x 20cm     |
| ZC2004                                                               | ZC2004*      | 5cm x 7cm       | ZC6009       | ZC6009*      | 15cm x 23cm     |
| ZC2004X                                                              | ZC2004X*     | 5cm x 7cm       | ZC6009X      | ZC6009X*     | 15cm x 23cm     |