# MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

| | |
|---|---|
| Company Name | : Bactiguard (South East Asia) Sdn. Bhd. |
| Company Address | : 308 b, Jalan Perindustrian Bukit Minyak 18, Penang Science Park, 14100, Penang Malaysia |
| Related Directive | : 93/42/EEC Medical Devices Directive |
| Definition of Change | : Company name has been changed to Bactiguard (South East Asia) Sdn. Bhd. |

| | |
|---|---|
| Number of Related Certificate | : M.2017.106.8971, M.2017.106.8971-1 |
| Report Number | : MD.3404 |
| Issue Date | : 30.12.2021 |
| Revision Date | : - |
| Revision Number | : 00 |

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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

**Address:** Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
**Phone:** +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
**E-mail:** info@udem.com.tr www.udem.com.tr

# EC CERTIFICATE

## Full Quality Assurance System

### Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2017.106.8971-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

| | |
|---|---|
| Company Name | : VIGILENZ Medical Devices Sdn. Bhd. |
| Company Address | : 308 b, Jalan Perindustrian Bukit Minyak 18, Penang Science Park, 14100 Penang, Malaysia |
| Related Directives and Annex | : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4) |
| Product | : Antimicrobial Wound Irrigation Solution - Class III |
| Models | : Hydrocyn aqua, Bactiguard Wound Care |
| GMDN | : 59523 |

This certificate has been designed due to Ministry of Health's 12.10.2017 dated and 80977004-511.14-E.203667 numbered scientific opinion, scope 93/42/AT Annex I Article 7.4

| | |
|---|---|
| Certificate Number | : M.2017.106.8971 |
| Report Number | : MD.3404.YB |
| Initial Assessment Date | : 26.01.2017 |
| Registration Date | : 03.11.2017 |
| Recertification Assessment Date | : 24.01.2020 |
| Reissue Date / No | : 27.08.2020/01 |
| Revision Date /No | : 25.05.2021/01 |
| Expiry Date | : 27.05.2024 |

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 93/42/EEC Directive 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. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

**Address:** Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
**Phone:** +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
**E-mail:** info@udemltd.com.tr www.udem.com.tr

# EC DESIGN EXAMINATION CERTIFICATE

## 93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2017.106.8971 the validity of the certificate M.2017.106.8971-1 will also end.

| | |
|---|---|
| Company Name | : VIGILENZ Medical Devices Sdn. Bhd. |
| Company Address | : 308 b, Jalan Perindustrian Bukit Minyak 18, Penang Science Park, 14100 Penang, Malaysia |
| Related Directives and Annex | : 93/42/EEC Medical Devices Directive - Annex II (Section 4) |
| Product | : Antimicrobial Wound Irrigation Solution - Class III |
| Models | : Hydrocyn aqua, Bactiguard Wound Care |
| GMDN | : 59523 |

This certificate has been designed due to Ministry of Health's 12.10.2017 dated and 80977004-511.14-E.203667 numbered scientific opinion, scope 93/42/AT Annex I Article 7.4

| | |
|---|---|
| Certificate Number | : M.2017.106.8971-1 |
| Report Number | : MD.3404.YB |
| Initial Assessment Date | : 26.01.2017 |
| Registration Date | : 03.11.2017 |
| Recertification Assessment Date | : 24.01.2020 |
| Reissue Date / No | : 27.08.2020/01 |
| Revision Date /No | :25.05.2021/01 |
| Expiry Date | : 27.05.2024 |

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

UDEM APPROVED 2292

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive 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 aforementioned directive. 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 validity of the certificate can be checked through www.udem.com. tr.

**Address:** Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
**Phone:** +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
**E-mail:** info@udemltd.com.tr www.udem.com.tr