
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.



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


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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 certificate 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 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



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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

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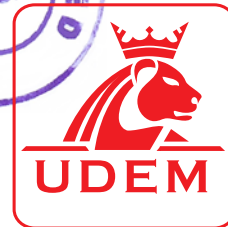
Recertification Assessment Date : 24.01.2020

Reissue Date / No : 27.08.2020/01

Revision Date /No :25.05.2021/01

Expiry Date : 27.05.2024

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The EC design 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.

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