CERTIFICATE

Full Quality Assurance System

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

M.2020.106.13506-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: ACTO GMBH
Company Address	: Büchnerstrasse 11, 38118 Braunschweig Germany
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-Sterile Polyhexanide containing, Actolind w Solution Wound Irrigation and Care Solution – Class III
GMDN	: 59523

This certificate has been designed due to Ministry of Health's 68869993-511.14-E.90442 numbered scientific opinion on 10.04.2020, scope 93/42/AT Annex I Article 7.4

Certificate Number	: M.2020.106.13506
Report Number	: MD.3709.IB
Initial Assessment Date	: 22.05.2019
Registration Date	: 13.04.2020
Revision Date /No	: -
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 applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the faremention 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 validity 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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CERTIFICATE

EC Design-Examination Certificate

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

With the expire of the certificate M.2020.106.13506 the validity of the certificate M.2020.106.13506-1 will also end.

Company Name : ACTO GMBH

Company Address : Büchnerstrasse 11, 38118 Braunschweig Germany

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

Product : Non-Sterile Polyhexanide containing, Actolind w Solution Wound Irrigation and Care Solution – Class III

GMDN : 59523

This certificate has been designed due to Ministry of Health's 68869993-511.14-E.90442 numbered scientific opinion on 10.04.2020, scope 93/42/AT Annex I Article 7.4

Certificate Number : M.2020.106.13506-1
Report Number : MD.3709.IB
Initial Assessment Date : 22.05.2019
Registration Date : 13.04.2020
Revision Date /No : -
Expiry Date : 27.05.2024

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

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 mapufacturer has established and applied 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 validity 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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