



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : İnvamed Sağlık İlaç San. ve Tic. A.Ş

Company Address : Alcı OSB Mah. 2010 Cad. Dış Kapı No:4 İç Kapı No:0 Sincan
ANKARA / TURKEY

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

Product : Atlas Peripheral Stent System - Class IIb, Sterile

GMDN : 47932

Product Types are attached.

Certificate Number : M.2020.106.13847
Report Number : MD.3091.IB
Initial Assessment Date : 15.11.2019
Registration Date : 28.08.2020
Revision Date /No : 10.05.2021/01
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 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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This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2020.106.13847 and with the registration date of 28.08.2020 and with the re-issue date 10.05.2021 issued for "İnvamed Sağlık İlaç ve Tic. 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 Directive.

REFERANCE NUMBER	NAME OF THE PRODUCT	GMDN CODE
ATS-05-020-6F-80	Atlas Peripheral Stent System 5mm*20mm*80cm, 6F	47932
ATS-05-020-6F-120	Atlas Peripheral Stent System 5mm*20mm*120cm, 6F	47932
ATS-05-040-6F-80	Atlas Peripheral Stent System 5mm*40mm*80cm, 6F	47932
ATS-05-040-6F-120	Atlas Peripheral Stent System 5mm*40mm*120cm, 6F	47932
ATS-05-060-6F-80	Atlas Peripheral Stent System 5mm*60mm*80cm, 6F	47932
ATS-05-060-6F-120	Atlas Peripheral Stent System 5mm*60mm*120cm, 6F	47932
ATS-05-080-6F-80	Atlas Peripheral Stent System 5mm*80mm*80cm, 6F	47932
ATS-05-080-6F-120	Atlas Peripheral Stent System 5mm*80mm*120cm, 6F	47932
ATS-05-100-6F-80	Atlas Peripheral Stent System 5mm*100mm*80cm, 6F	47932
ATS-05-100-6F-120	Atlas Peripheral Stent System 5mm*100mm*120cm, 6F	47932
ATS-05-120-6F-80	Atlas Peripheral Stent System 5mm*120mm*80cm, 6F	47932
ATS-05-120-6F-120	Atlas Peripheral Stent System 5mm*120mm*120cm, 6F	47932
ATS-05-150-6F-80	Atlas Peripheral Stent System 5mm*150mm*80cm, 6F	47932
ATS-05-150-6F-120	Atlas Peripheral Stent System 5mm*150mm*120cm, 6F	47932
ATS-06-020-6F-80	Atlas Peripheral Stent System 6mm*20mm*80cm, 6F	47932
ATS-06-020-6F-120	Atlas Peripheral Stent System 6mm*20mm*120cm, 6F	47932
ATS-06-030-6F-80	Atlas Peripheral Stent System 6mm*30mm*80cm, 6F	47932
ATS-06-030-6F-120	Atlas Peripheral Stent System 6mm*30mm*120cm, 6F	47932
ATS-06-040-6F-80	Atlas Peripheral Stent System 6mm*40mm*80cm, 6F	47932
ATS-06-040-6F-120	Atlas Peripheral Stent System 6mm*40mm*120cm, 6F	47932
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ATS-06-150-6F-80	Atlas Peripheral Stent System 6mm*150mm*80cm, 6F	47932
ATS-06-150-6F-120	Atlas Peripheral Stent System 6mm*150mm*120cm, 6F	47932
ATS-06-200-6F-120	Atlas Peripheral Stent System 6mm*200mm*120cm, 6F	47932
ATS-07-020-6F-80	Atlas Peripheral Stent System 7mm*20mm*80cm, 6F	47932
ATS-07-020-6F-120	Atlas Peripheral Stent System 7mm*20mm*120cm, 6F	47932
ATS-07-020-6F-80	Atlas Peripheral Stent System 7mm*20mm*80cm, 6F	47932
ATS-07-020-6F-120	Atlas Peripheral Stent System 7mm*20mm*120cm, 6F	47932
ATS-07-030-6F-80	Atlas Peripheral Stent System 7mm*30mm*80cm, 6F	47932
ATS-07-030-6F-120	Atlas Peripheral Stent System 7mm*30mm*120cm, 6F	47932
ATS-07-040-6F-80	Atlas Peripheral Stent System 7mm*40mm*80cm, 6F	47932
ATS-07-040-6F-120	Atlas Peripheral Stent System 7mm*40mm*120cm, 6F	47932
ATS-07-060-6F-80	Atlas Peripheral Stent System 7mm*60mm*80cm, 6F	47932
ATS-07-060-6F-120	Atlas Peripheral Stent System 7mm*60mm*120cm, 6F	47932
ATS-07-080-6F-80	Atlas Peripheral Stent System 7mm*80mm*80cm, 6F	47932



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ATS-07-100-6F-120	Atlas Peripheral Stent System 7mm*100mm*120cm, 6F	47932
ATS-07-120-6F-80	Atlas Peripheral Stent System 7mm*120mm*80cm, 6F	47932
ATS-07-120-6F-120	Atlas Peripheral Stent System 7mm*120mm*120cm, 6F	47932
ATS-07-150-6F-80	Atlas Peripheral Stent System 7mm*150mm*80cm, 6F	47932
ATS-07-150-6F-120	Atlas Peripheral Stent System 7mm*150mm*120cm, 6F	47932
ATS-07-200-6F-120	Atlas Peripheral Stent System 7mm*200mm*120cm, 6F	47932
ATS-08-020-6F-80	Atlas Peripheral Stent System 8mm*20mm*80cm, 6F	47932
ATS-08-020-6F-120	Atlas Peripheral Stent System 8mm*20mm*120cm, 6F	47932
ATS-08-030-6F-80	Atlas Peripheral Stent System 8mm*30mm*80cm, 6F	47932
ATS-08-030-6F-120	Atlas Peripheral Stent System 8mm*30mm*120cm, 6F	47932
ATS-08-040-6F-80	Atlas Peripheral Stent System 8mm*40mm*80cm, 6F	47932
ATS-08-040-6F-120	Atlas Peripheral Stent System 8mm*40mm*120cm, 6F	47932
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ATS-08-100-6F-80	Atlas Peripheral Stent System 8mm*100mm*80cm, 6F	47932
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