

CERTIFICATE OF CONFORMITY  
WITH EUROPEAN DIRECTIVE



Certificate No.: EU0707419

Order No.: 86269

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12<sup>th</sup> January 1995 relating to medical devices pursuant to act no. 6 of 12<sup>th</sup> January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer: **APPLIED TRADING FZE**  
P-6/164,  
P.O. Box 120066  
Saif Zone, SHARJAH, United Arab Emirates

Device category: Medical Devices

GMDN code: See Appendix 1 to this certificate

Models: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIa

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC, with the exemption of section 4.

Date of audit: 16<sup>th</sup> April 2007

Date of the end of the validity: 1<sup>st</sup> September 2012

Nemko EC notification No.: 0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2007-08-02

Date of verification: 2007-08-02

Signature: Svein Grahnstedt  
MD PhD Senior Lead Auditor

Signature: Frank Skarpsno  
Per Senior Lead Auditor / Principal Engineer

**CE 0470**

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Device category: Medical Devices / Medical Disposables

**Appendix 1: Page 1 of 1**

The certificate referred to above includes the following devices/models:

SNO	PRODUCT	CLASS	STERILE	GMDN CODE
1	Blood Transfusion Set / I.V Set	Ila	YES	10421
2	IV Set	Ila	YES	16649
3	Feeding Tubes	Ila	YES	14199
4	Ryles Tube	Ila	YES	14208
5	Foley Catheter	Ila	YES	10720
6	Liv-O-Flex	Ila	YES	14242
7	Measured Volume Extractor	Ila	YES	15111
8	T-Tube	Ila	YES	17840
9	Transparent Gloves	Ila	YES/NO	33517
10	Urine Collection Bags	Ila	YES	14298
11	Levine Tube	Ila	YES	32228
12	Spike	Ila	YES	15275
13	Supra Cath	Ila	YES	16420
14	Manifolds	Ila	YES	15042
15	C.V.P. Set	Ila	YES	16864
16	Life-O-Flow	Ila	YES	30865
17	Scalp Vein Set	Ila	YES	12752
18	Blood Donor Set	Ila	YES	10426
19	Dome	Ila	YES	15293

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Per Signature: Frank Skarpsno