

DECLARATION OF CONFORMITY

MANUFACTURER:

**ELMASLAR İMALAT TIBBİ CİHAZ İNŞAAT TAŞIMACILIĞI İTHALAT İHRACAT
SANANAYİ VE TİCARET ANONİM ŞİRKETİ**
1. ORGANİZE SANAYİ BÖLGESİ, BABÜRŞAH CADDESİ,
NO: 17, SINCAN, ANKARA, TÜRKİYE

PRODUCTS:

Product Name	Model	UMDN Code	Classification	Rule
Oxygen Concentrator	Healthtime OC-5 PLUS	12873	Ila	Annex-V of the Directive 93/42/EEC on medical device
Nebulizers	Nebtime UN 600A, UN 300A, CN 01, CN 02 & CN 04	12712	Ila	
Sleep Apnea Device	Sleeptime/Sleeptime Plus CPAP/APAP/BPAP	11001	Ila	
Surgical Aspirator	Lifetime SA 01HT/ SA 01/02/03PT & SA 01/02/03/04PB	10217	Ila	
Mask for CPAP-BPAP	Sleeptime F. Face / Nasal	12447		

We, hereby declare that we will look after the proper application of the quality system earmarked for design, production and final inspection of the medical equipment stipulated below.

We do assure and declare that the aforementioned products meet requirements of Medical Device Directive 93/42/EEC Annex V concerning medical equipment and that we have been familiarized ourselves with a result of design documentation evaluation and that we have been authorized to use "CE" mark with identification number: 1984.

STANDARED APPLIED: The applicable section of the following standard for safely and quality were applied: ISO 9001: 2008; ISO 13485: 2003 and CE 1984

NOTIFIED BODY:

KIWA MEYER CERTIFICATION SERVICES INC.

İTOSB 9. CAD. NO: 15 TEPEÖREN – TUZLA / İSTANBUL – TÜRKİYE

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CERTIFICARES: ISO 9001:2008; No: M 7622

ISO 13485:2003; No: M 7623

CE 1984 NO: 1984-MDD-09-002

ELMASLAR
İMALAT TIBBİ CİHAZLAR İNŞ.
TAŞ.İTH.İHR.SAN. VE TİC.A.Ş.
1. Organize Sanayi Bölgesi Babürşah Caddesi No: 17
Tel: 0312 394 80 01 Fax: 394 80 04 Sincan/ANKARA
Sincan Vergi Dairesi - 333 064 6224

02.11.2017

ANKARA / TURKEY

Cemal Şahin

General Manager / Elmaslar A.Ş.