

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 No.	UMDN Code	Classification	Rule
Healthtime PLUS Oxygen Concentrator	OC-5	12873	Ila	Annex-V of the Directive 93/42/EEC on medical device
Nebtime Ultrasonic and Compressure Nebulizers	UN 600A, UN 300A & CN 01/02/03/04	12712	Ila	
Sleeptime/Sleeptime Plus Sleep Apnea Devices	CPAP/APAP/ BPAP	11001	Ila	
Lifetime Surgical Aspirators	SA 01HT, SA 01/02/03PT & SA 01/02/03/04PB	10217	Ila	
Sleeptime F. Face / Nasal Masks	Full Face and 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.

STANDARD APPLIED: The applicable section of the following standard for safety and quality were applied: ISO 9001: 2015; ISO 13485: 2016 and CE 1984

NOTIFIED BODY: **KIWA CERTIFICATION SERVICES INC.**

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

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CERTIFICATES: ISO 9001:2015; No: M 11118

ISO 13485:2016; No: M 7623

CE 1984 NO: 1984-MDD-09-002

02.01.2019

ANKARA / TURKEY

ELMASLAR
İMALAT TIBBİ CİHAZLAR İNŞ.
TAŞ.İTH.İHR.SAN. VE TİC.A.Ş.
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Sincan Vergi Dairesi - 333 064 6224

Cemal Şahin

General Manager / Elmaslar A.Ş.