



# Certificate of Compliance

This is to certify that

**Name and Address of Registered Manufacturer:** KIRLANGIC TEMIZLIK TAŞIMACILIK VE INS. SAN. LTD. STI  
**Product Name:** ERENLER MAH. 1240 SOK. NO:4 ERENLER SAKARYA TURKIYE  
**Product type/model:** INFRARED THERMOMETER  
**Trade mark:** AKET.KRLN.002-00  
MIDISIS

**This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.**

**Relevant EC Directive:** Medical Device Directive 93/42/EEC  
**Conformity assessment procedure:** EC Declaration of Conformity ( Directive 93/42/EEC)  
**Classification:** Class I of Directive 93/42/EEC  
**Applied normative documents:** EN 60601-1:2006+A1:2013+A12:2014,  
EN 60601-1-11:2015, EN 60601-1-2: 2015,  
EN 55011: 2016/A1: 2017  
**Applied Quality Management System:** N/A

This AoC will remain valid only if Quality Management System Certificate remains valid. The assessment process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test report made by:

- KIRLANGIC MAKINA
- No. of test report:** AKE-KK-091020  
**Issue date:** 09.10.2020

The mutual obligations and rights of the certification are regulated by the contract No. EAS/CE/XXXX. This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

**Certificate no.:** EUAC/CE/XXXX-XXXX  
**Issued on:** DD/MM/YYYY  
**Validity Until:** DD/MM/YYYY  
**1<sup>st</sup> Surveillance Due On:** DD/MM/YYYY  
**2<sup>ND</sup> Surveillance Due On:** DD/MM/YYYY

**AUTHORISED BY**  
**CHAIRMAN/DIRECTOR**  
**P.C. MANAGEMENT SYSTEM PVT. LTD.**

THE VALIDITY OF CERTIFICATE IS SUBJECT TO REGULAR SURVEILLANCE AUDIT ON OR ABOVE MENTIONED DATES AND IT'S ONLY VALID AFTER SUCCESSFUL SURVEILLANCE WITH CONTINUATION LETTER ISSUED BY PCMS.

TO VERIFY THIS CERTIFICATE STATUS PLEASE VISIT ACCREDITATION BOARD WEBSITE [www.europeanaccreditationservices.com](http://www.europeanaccreditationservices.com)

CE



Acc No.:- EUAC110



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The Certificate Remains The Property Of PCMS As Per Certificate Audit Contract