



EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

EARTEKNIK ISITME VE ODIOMETRI CIHAZLARI SAN. vE TIC. A.S

AVRUPA SERBEST BÖLGESİ SUBESİ,
113 Ada, 1. Parsel, No 22/3
59860 Corlu - Tekirdag,
Ikitelli V.D. 323 029 0629
Corlu - Tekirdag,
Turkey

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Device family	Device	Class
Hearing aids	BTE hearing aids faceplates for ITE-products	Ila Ila

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	284474 MR5
Certificate unique ID	170610211
Effective date	2015-02-28
Expiry date	2020-02-27
Frankfurt am Main	2015-02-28

DQS Medizinprodukte GmbH

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Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.