

DECLARATION OF CONFORMITY



otometrics

According to:

The Medical Devices Directive 93/42/EEC, annex II

Product description

Otoacoustic Emissions and Automated ABR Screener.

Model

23 June 2010

AccuScreen TE, AccuScreen DP,
AccuScreen TE/DP, AccuScreen ABR,
AccuScreen ABR/TE, AccuScreen ABR/DP,
AccuScreen ABR/TE/DP, AccuScreen Lite TE,
AccuScreen Lite DP

Type

Type 1077

Brand

GN Otometrics

Classification

Class IIa

Notified Body & CE-mark

LNE/G-MED, CE 0459

Manufacturer's name, address, telephone & fax no.

GN Otometrics A/S
Dybendalsvænget 2
DK-2630 Taastrup
Denmark

Telephone +45 72 111 555
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As the manufacturer, we declare in good faith that the above-mentioned equipment complies with the provisions of the directive stated above.

Taastrup
Place

23 June 2010
Date

Asif Muhammad
Signature

Name and title: *Asif Muhammad, Regulatory Manager*

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