

The management system of

# OTODYNAMICS LTD

36-38 Beaconsfield Road, Hatfield, Hertfordshire, AL10 8BB, UK

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

**Otoport Handheld Otoacoustic Emission Analyser System**

**Echoport USB Otoacoustic Emission Analyser System**

for use in the analysis and diagnosis of hearing loss.

**ILOv6 Clinical Otoacoustic Emission Software for use with Echoport USB.**

**EZ-Screen 2 Otoacoustic Emission Screening and Data Management Software**

for use with Echoport USB.

**Auditory Brainstem Response Unit for use with the Otoport Handheld**

**Otoacoustic Emission System in hearing screening**

for the early identification of hearing loss.

**OtoNova OAE and ABR Analyser System for Use in the Analysis**

**and Diagnosis of Hearing Loss with Nova- Link Software for Screening,**

**Diagnosis and Data Management**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 14 May 2021 until 02 August 2023 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 12 September 1997

Certification is based on reports numbered GB/PC 05615

Authorised by

Global Medical Devices Head of Notified Body

### SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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# OTODYNAMICS LTD

36 – 38 Beaconsfield Road, Hatfield, Hertfordshire, AL10 8BB, UK

## Scope:

Otoport Handheld Otoacoustic Emission Analyser System Echoport USB  
Otoacoustic Emission Analyser System for use in the analysis and diagnosis of  
hearing loss. ILOv6 Clinical Otoacoustic Emission Software for use with Echoport  
USB. EZ-Screen 2 Otoacoustic Emission Screening and Data Management  
Software for use with Echoport USB. Auditory Brainstem Response Unit for use with  
the Otoport Handheld Otoacoustic Emission System in hearing screening for the  
early identification of hearing loss. OtoNova OAE and ABR Analyser System for Use  
in the Analysis and Diagnosis of Hearing Loss with Nova- Link Software for  
Screening, Diagnosis and Data Management

This corrigendum is only valid together with accompanying 93/42/EEC certificate  
issue 2

<b>Correction date</b>	<b>Correction</b>
Change approved by SGS on the 7 <sup>th</sup> of February 2023	– Annex II – Change of registered address to - 30-38 Beaconsfield Road, Hatfield, Hertfordshire, AL10 8BB, UK by way of corrigendum.

Authorised by

Global Medical Devices Certification Manager

## SGS Belgium NV, Notified Body 1639

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LPMD5105 Corrigendum to a CE1639 MDD Certificate

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SGS Belgium NV

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