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

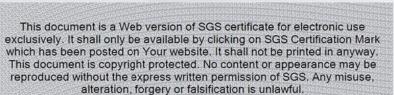
SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 1







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

Correction date	<u>Correction</u>
Change approved by SGS on the 7th of February 2023	

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5105 Corrigendum to a CE1639 MDD Certificate

Page 1 of 1

SGS Belgium NV

Certification and Business Enhancement Maatschappelijke Zetel/Siège Social: Noorderlaan 87 B-2030 Antwerpen/Anvers t +32 (0)3 545 48 48 f +32 (0)3 545 48 49

<u>I.be.sqs.com</u> Member of the SGS Group

RPR Antwerp VAT - BE 0404.882.750 Citibank BE87 5701 3412 5594