EC Certificate Full Quality Assurance System: Certificate GB19/964725

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

Corrigendum to Certificate GB19/964725

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

Authorised by

Global Medical Devices Certification Manager

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