Medical Device Full Quality Assurance System Certificate GB24/00000028

The management system of

OTODYNAMICS LTD

30-38 Beaconsfield Road Hatfield Hertfordshire AL10 8BB United Kingdom
has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 01 February 2024 until 01 February 2029 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 01 February 2024

L. Henderson

Authorised by
Lynn Henderson

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OTODYNAMICS LTD

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

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 Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Previous certificate number: N/A
Change in between this certificate and previous one: N/A