OTODYNAMICS LTD
30-38 Beaconsfield Road
Hatfield, Hertfordshire
AL10 8BB
United Kingdom- UK

19/01/2024

Confirmation Letter Reference: CLNB1639 GBPC 05615

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

OTODYNAMICS LTD
30-38 Beaconsfield Road
Hatfield, Hertfordshire
AL10 8BB
United Kingdom
SRN: GB-MF-000018964

Authorized representative:
Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
Hannover 30175
Germany
SRN: DE-AR-000005430

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

pp [Haldun OGUZ]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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. 506039617ECHOPORTTE	Class IIa	N/A	GB19/964725; NB1639
Otoport Handheld Otoacoustic Emission Analyser System for use in the analysis and diagnosis of hearing loss. Auditory Brainstem Response Unit for use with the Otoport Handheld Otoacoustic Emission System in hearing screening for the early identification of hearing loss. 506039617OTOPORTVJ	Class IIa	N/A	GB19/964725; NB1639
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. 506039617OTONOVAUA	Class IIa	N/A	GB19/964725; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
19/01/2024	Version 1	Initial issue
14/02/2024	Version 2	revision of the name of the devices in line with the MDD certificate