# MANUFACTURER'S EU DECLARATION OF CONFORMITY- DoC - Echoport
# EU EC DoC

FULL QUALITY ASSURANCE PROCEDURES
This is a declaration of conformity (according to EN ISO/IEC 17050-1:2010 and current medical device regulations).

**Manufacturer's name:** **OTODYNAMICS LTD**

**Business address:** 30-38 Beaconsfield Rd
Hatfield, Hertfordshire- Herts
AL10 8BB, United Kingdom- UK

**Responsibility Statement:** This EU declaration of conformity is issued under the sole responsibility of Otodynamics Ltd. Otodynamics Ltd declares that the Echoport product (s) covered in this document are in conformance with the MDD/ EU MDR requirements as amended.

**Medical device(s):** **Echoport** USB Otoacoustic Emission- OAE Analyser System for use in the analysis and diagnosis of hearing loss.
ILOv6 Clinical OAE Software for use with **Echoport** USB.
EZ- Screen 2 OAE Screening and Data Management Software for use with **Echoport** USB.

**Classification:** **Class IIa** under rule 10 of Medical Device Directive [93/42/EEC] & [MEDDEV 2. 4/1 Rev. 9]

**GMDN code and term:** (58018) _Otoacoustic Emission System, Line-Powered

**UMDNS Code and term:** (17601) _ Auditory Function Screening Devices

**European Medical Device Nomenclature (EMDN):** (Z12149001)_Otoacoustic Emissions Equipment

**Scope of application:** Current OAE **Echoport** USB Product Variants

| Variant Names | Variant Code | UDI-DI (GTIN-14), GS1 | EUDAMED DI* | Basic UDI-DI** (GS1 Global Model Number- GMN) |
|---|---|---|---|---|
| **ECHOPORT 288 I** | **288USB-I** | **05060396170195** | B-05060396170195 | 506039617ECHOPORTTE |
| **ECHOPORT 288 II** | **288USB-II** | **05060396170201** | B-05060396170201 | |
| **ECHOPORT 292 I** | **292USB-I** | **05060396170218** | B-05060396170218 | |
| **ECHOPORT 292 II** | **292USB-II** | **05060396170225** | B-05060396170225 | |

**Note:** The **ECHOPORT** Product variant names were previously known as:
**ECHOPORT** 288 USB I or II; **ECHOPORT** ILO288 USB I or II;
**ECHOPORT** 292 USB I or II; **ECHOPORT** ILO292 USB I or II.
*: Legacy MDD device registration in EUDAMED per the requirements of "MDCG 2019-5, Registration of legacy devices in EUDAMED".
**: Basic UD-DI for the EU MDR Device

**European Union Authorized Representative AR**

EC REP

MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany

CE 1639

F-008-37REV003.2 14/02/2024

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## Current Good Manufacturing Practices- cGMP Statement

The Otodynamics UK facility, located in Hatfield, Herts, manufactures a range of OAE & ABR medical devices that are globally distributed to healthcare industry. Products manufactured at our Otodynamics UK facility are produced using applicable medical devices cGMP based on EN ISO 13485: 2016+A11:2021, FDA 21CFR820 and regulations. Otodynamics operates under a state of continuous quality control per regulations and the QMS reflects activities associated with product design, manufacture, distribution and service.

- MHRA- Medicines and Healthcare products Regulatory Agency is the Competent Authority- CA in the UK.
- The authorized Notified body SGS Belgium NV (NB 1639) carries out the EU MDR [2017/745] conformity assessment procedures on the medical devices.
- SGS UK Ltd carries out the QMS EN ISO 13485 conformity assessment procedures on the company.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

## Full Quality Assurance procedures certificate:

Otodynamics EC Certificate Full Quality Assurance System: SGS Certificate GB19/964725
European Conformity assessment certificate under Annex II (excluding Section 4) of the Directive 93/42/EEC (MDD) on Medical Devices.
The Certificate was valid from 14 May 2021 until 02 August 2023 (Expired).

- SGS NB1639 Confirmation Letter Extension of MDD certificate Reg. (EU) 2023/607, Reference: CLNB1639 GBPC 05615, Version 2 on 14/02/2024.

**Notified Body:** SGS Belgium NV (NB 1639), SGS House Noorderlaan, 87 2030, Antwerp, Belgium.

## Otodynamics Declaration of validity of MDD Certificate- MDR Transition

- **Otodynamics Declaration on validity of MDD certificate- MDR Transition_rev20-09-2023_Expires 31-12-2028.**
  - Otodynamics products/ services are in compliance with the EU MDR and other regulations on no significant changes in the design and intended purpose; that is, it is evident that since the date of Application of EU MDR of 26 May, 2021 there are No significant changes made to the design/ intended purpose of the Echoport products per the requirements of [MDCG-2020-3_Rev1, May 2023].
  - Currently revised the "EU MDR Article 120", states that devices which continue to comply with the MDD may be placed on the market or put into service **until 31 December 2028** (for Class IIa Medical Devices such as Echoport) provided the conditions set out in Article 120 (3c) MDR are fulfilled.
  - Regulation EU 2023/607 of 20 March 2023 amended MDR by extending the MDR transition timeline while recognising as valid previously issued MDD certificates for the duration of those longer transition timelines.

**QMS:** EN ISO 13485:2016 & EN ISO 14971:2019. SGS Certificate: GB97/10852, Valid from 01 February 2024 until 01 February 2027. Issue 20. Certified since 12 September 1997.
SGS United Kingdom Ltd, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK.

## Declarations/ Regulations applied:

The **Echoport USB** and ILOv6 Clinical OAE Software and EZ-Screen 2 (also known as EZscreen) OAE Screening and Data Management Software products are declared to be in compliance with the council directives 93/42/EEC Annex II (excluding Section 4), 93/68/EEC, 2001/104/EC & 2007/47/EC [MDD] and in transition consideration of new Regulation (EU) 2017/745 of 5 April 2017 [MDR] on medical devices (taking account of the intended purpose of the devices concerned).

- **We confirm that the Echoport medical devices we supply EU are compliant with the applicable requirements of MDR 2017/745/EU. The Echoport medical devices will maintain CE mark under MDD, as established by MDR *Article 120 - Transitional Provisions*, and will be certified according to MDR before this DoC expiry date of 31 December 2028.**
  - An application for Echoport MDR certification is submitted to SGS NB1639: "REV10_LPMDREG1010 Product Information Questionnaire Rev10_V1_Echoport signed".
  - The current SGS EU MDR contract is "Otodynamics_GBPC_7309_EUMDR Proposal_signed_2023-11-28T11-28-00Z".

In addition, these **Echoport USB** products comply with the requirements of REACH Regulation EC) No 440/2008 & (EC) No 1907/2006; of the WEEE Directive 2012/19/EU; of the RoHS Directive 2011/65/EU (RoHS 2) and "Packaging Directive" 94/62/EC.



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**Declared Conformance to the following standards:**

**Safety**: EN 60601-1:2006+A2:2021 (IEC 60601-1, ed. 3.2); EN 60601-1-6:2010+A2:2021 (IEC 60601-1-6, ed. 3.2); EN 62366-1:2015+A1:2020 (IEC 62366-1, ed.1.1); EN 62304: 2006+ A1:2015; PD ISO/ TR 80002-2: 2017.
**EMC**: EN 60601-1-2:2015 +A1:2021 (IEC 60601-1-2, ed. 4.1).
**Other:** EN/IEC 60645-1:2017; EN/IEC 60645-3:2020; EN/IEC 60645-6:2022; EN ISO 10993-1:2020; EN IEC 63000:2018; EN 50419:2022; EN ISO/IEC 17050-1:2010; EN ISO 20417:2021; EN ISO 15223-1:2021; EN ISO 14155: 2020; EN 60601-1-9:2008+A2:2020; EN ISO 14001:2015; EN ISO 14040:2006+A1:2020; EN ISO/IEC 27001:2022; EN ISO 27799:2016; ISO/IEC 27032:2012; EN 62353:2014; ISTA Procedure 3A (18-18); ASTM D4332 – 14.

**Materials Declarations/ Conformity:**

**Echoport USB** products do not contain any of the restricted substances in concentrations/ applications not permitted by the RoHS Directive (maximum concentration values tolerated by weight in homogeneous Materials):

- Cadmium (Cd- 0.01 %); Lead (Pb – 0.1 %); Hexavalent Chromium ($Cr^{6+}$- 0.1 %); Mercury (Hg- 0.1 %);
- PBB's (Polybrominated biphenyls) (PBB- 0.1 %); PBDE's (Polybrominated diphenyl ethers) (PBDE 0.1 %);
- Adaptation of RoHS Directive issued (2015/863/EU) for the four additional phthalate substances:
- Bis (2-ethylhexyl) phthalate (DEHP – 0.1%); Butyl benzyl phthalate (BBP – 0.1%); Dibutyl phthalate (DBP – 0.1%);
- Diisobutyl phthalate (DIBP – 0.1%).
- Otodynamics **Echoport USB** products do not contain phthalates.
- No Ozone Depleting Substances are used by Otodynamics/ its Products.
- None of the following are used by Otodynamics/ its Products: Polychlorinated Biphenyls (PCBs); Chlorinated Paraffins; brominated flame retardants, asbestos, chlorofluorocarbons (CFC's), hydrochlorofluorocarbons (HCFC's), hydrofluorocarbons (HFC's), Tributyl Tin (TBT); Triphenyl Tin (TPT) and Tributyl Tin Oxide (TBTO).
- Otodynamics products do not contain Latex and do not contain Materials Derived from Animal Sources.
- Materials used in the manufacturing processes for the Otodynamics products are Not Substances of Very High Concern (SVHC) and are in line with REACH regulations.

The **Echoport USB** product packaging is reusable. The **Echoport USB** medical device/ system is not supplied sterile or intended to be sterilized by the user. It is recommended that probe Ear Tips are for single PATIENT use only.

**Echoport System Items:**

The Ear probes and the below items are part of the Echoport device system- together they are a class IIa medical device. UGS/ UGD Probes/ Spares (Body/ Lid & Coupler Tubes), Probe Ear Tips; Probe Cable Clip; Test Cavity; USB 2.0 Cables; Carry Case; Calibration Unit (dealers only); when requested recommended PC/ Laptop medical power supply, when requested recommended PC/ Laptop. More details are provided in the Echoport product manual. Reference the "F-008-55 Echoport Technical, Clinical Description & Declaration – DoC attachment Rev001 attachment document to this EU DoC for the complete list of Echoport items.

**Authorised signatory:** person responsible for regulatory compliance-prrc. **Place of Issue:** Otodynamics Ltd, Hatfield, Hertfordshire, United Kingdom.

| Anastasios Parasiris | Product Quality Assurance & Regulatory Assurance Manager | Anastasios Parasiris | 14/02/2024 |
|---|---|---|---|
| *Name* | *Position* | *Signature* | *Date (DD/MM/YYYY)* |



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