MANUFACTURER'S 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, Herts
AL10 8BB, UK

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 rules 5 & 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: (10228) _ Audiometers;
(17601) _ Auditory Function Screening Devices.

CND Structure Z121401: *AUDIOMETERS*
Z12149001: *AUDITORY FUNCTION SCREENING DEVICES*

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

Variant Names	Variant Code	UDI (GTIN-13)
ECHOPORT 288 I	**288USB-I**	**5060396170195**
ECHOPORT 288 II	**288USB-II**	**5060396170201**
ECHOPORT 292 I	**292USB-I**	**5060396170218**
ECHOPORT 292 II	**292USB-II**	**5060396170225**

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.

European Union Authorized Representative AR

EC REP

MDSS GmbH
Schiffgraben 41, 30175 Hannover, Germany

CE 1639

F-008-37REV002 25/05/2021

Otodynamics Ltd
30-38 Beaconsfield Road
Hatfield, Herts.
AL10 8BB UK

t. +44 (0)1707 267540
f. +44 (0)1707 262327
t. 1 800 659 7776 USA
e. info@otodynamics.com

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, FDA 21CFR820 and regulations. Otodynamics operates under a state of continuous quality control per regulations and the Quality Management System- QMS reflects activities associated with product design, manufacture, sales, 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 Directive 93/42/EEC on medical devices conformity assessment procedures.
- The authorized Notified body SGS UK Ltd (NB 0120) carries out the QMS EN ISO 13485: 2016 conformity assessment procedures.

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 on Medical Devices. The Certificate is valid from 14 May 2021 until 02 August 2023.
Notified Body: SGS Belgium NV (NB 1639), SGS House Noorderlaan, 87 2030, Antwerp, Belgium.
QMS: EN ISO 13485:2016 & EN ISO 14971:2019. Certificate: GB97/10852 (Valid from 20 August 2020 until 02 August 2023).
Notified Body: SGS United Kingdom Ltd, Notified Body 0120, Rossmore Business Park Ellesmere Port, Cheshire, CH65 3EN, UK.

Regulations/ Standards 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 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 02 August 2023.**

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.

Declared Conformance to the following standards:

Safety: EN 60601-1:2006+ A12:2014; IEC 60601-1:2005/AMD1:2012/COR; EN 60601-1-6:2010+ A1:2015; EN 62366-1:2015; EN 62304: 2006+ A1:2015; PD ISO/ TR 80002-2: 2017.
EMC: EN 60601-1-2:2015; IEC 60601-1-2:2014, ed. 4.0.
Other: EN 60645-1:2017, EN 60645-3:2020; EN 60645-6:2010; EN ISO 10993-1:2020; EN IEC 63000:2018; EN IEC 62430:2009; EN 50419:2006; EN ISO/IEC 17050-1:2010; EN ISO 20417:2021; EN ISO 15223-1:2016; EN ISO 14155: 2020; EN 60601-1-9:2008+ A2:2020; EN ISO 14001:2015; EN ISO 14040: 2006+A1:2020; EN ISO/IEC 27001:2017; EN ISO 27799:2016; ISO/IEC 27032:2012; EN 62353:2014; ISTA Procedure 3A (18-18); ASTM D4332 – 14.

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%);

Otodynamics Ltd
30-38 Beaconsfield Road
Hatfield, Herts.
AL10 8BB UK

t. +44 (0)1707 267540
f. +44 (0)1707 262327
t. 1 800 659 7776 USA
e. info@otodynamics.com

- 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:

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 product manual

Authorised signatory: person responsible for regulatory compliance

Anastasios Parasiris	Product Quality Assurance Manager		25/05/2021
Name	*Position*	*Signature*	*Date (DD/MM/YYYY)*

Otodynamics Ltd
30-38 Beaconsfield Road
Hatfield, Herts.
AL10 8BB UK

t. +44 (0)1707 267540
f. +44 (0)1707 262327
t. 1 800 659 7776 **USA**
e. info@otodynamics.com

Registered in England • Company No: 2289571 • VAT No: GB 539 9876 66 • FDA Region: 8021990 • Producer Reg No: WEE/BF035QU