MANUFACTURER'S DECLARATION OF CONFORMITY- DoC - Otoport United Kingdom- UK [UK DoC- Otoport]

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity according to EN ISO/IEC 17050-1:2010 and UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Manufacturer's name: **OTODYNAMICS LTD**

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

Responsibility Statement: This UK declaration of conformity is issued under the sole responsibility of Otodynamics Ltd. Otodynamics Ltd declares that the Otoport product (s) covered in this document are in conformance with the requirements of UK MDR 2002 (SI 2002 No 618, as amended).

Medical device(s): **Otoport** Otoacoustic Emission- **OAE** and Auditory Brainstem Response- **ABR** Analyser System for Use in the Analysis and Diagnosis of Hearing Loss with Otolink Software for Data Management.

Classification: **Class IIa** under rule 10 of Annex IX of Directive 93/42.

GMDN code/ term: (35747) _Evoked-potential audiometer;
(58019) _Otoacoustic emission system, battery-powered.

UMDNS Code/ term: (17601) _ Auditory Function Screening Devices;
(16303) _ Audiometric Evoked-Potential Units.

EU Medical Device Nomenclature (EMDN): (Z12149001)_Otoacoustic Emissions Equipment;
(Z12140302)_ Evoked Potential Audiometry Equipment.

Scope of Application: Current **Otoport** Product Variants

Variant Name	Variant Code	UDI- DI (GTIN-14, GS1)	Basic UDI-DI (GS1 Global Model Number-GMN)
OTOPORT OAE			
OTOPORT ADVANCE	ADV-S	05060396170119	506039617OTOPORTVJ
OTOPORT FLEXI	FLX-S	05060396171208	
OTOPORT TE SCREENER	OS-ST	05060396171055	
OTOPORT LITE DP	LTC-SD	05060396170027	
OTOPORT LITE TE	LTC-ST	05060396170003	
OTOPORT NHSP OAE	NHSP-OS-ST	05060396171093	
OTOPORT NBHSW OAE	NBHSW-OS-ST	05060396171659	
OTOPORT OTOCHECK OAE			
OTOCHECK LE TE	LE-ST	05060396170171	506039617OTOPORTVJ
OTOCHECK LE DP	LE-SD	05060396170188	
OTOPORT OAE+ABR			
OTOPORT ADVANCE + ABR	ADV-S+ABR	05060396170126	506039617OTOPORTVJ
OTOPORT FLEXI + ABR	FLX-S +ABR	05060396171215	
OTOPORT TE SCREENER + ABR	OS-ST+ABR	05060396171062	
OTOPORT LITE DP + ABR	LTC-SD+ABR	05060396170034	
OTOPORT LITE TE + ABR	LTC-ST+ABR	05060396170010	
OTOPORT NHSP OAE+ABR SCREENER	NHSP-OS-ST+ABR	05060396171109	
OTOPORT NBHSW OAE+ABR SCREENER	NBHSW-OS-ST+ABR	05060396172335	
OTOPORT ABR			
OTOPORT LITE ABR SCREENER	LTC-ABR	05060396170133	506039617OTOPORTVJ
OTOPORT NHSP ABR SCREENER	NHSP-OS-ABR	05060396171086	

In Otoport ABR requirements are met by the **Otoport+**ABR system. NBHSW for UK Only.

UK CA 0120

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, Hertfordshire, 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 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 UK Approved Body SGS UK Ltd (AB 0120) carries out the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) 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 UK CA Certificate Full Quality Assurance System: SGS Certificate GB24/00000028

United Kingdom Conformity assessment certificate under procedures performed based on Part II of United Kingdom- UK Medical Devices Regulations- MDR 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to the UK MDR 2002]. (Audit of Full Quality Assurance- QMS/ Technical Documentation).

The Certificate is valid from 01 February 2024 until 01 February 2029. Issue 1. Certified since 01 February 2024.

Approved Body: SGS United Kingdom Ltd, AB0120, Rossmore Business Park Ellesmere Port, Cheshire, CH65 3EN, UK.

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 **Otoport** and Otolink Software for data management products are declared to be in compliance with current UK MDR 2002 on medical devices as amended (taking account of the intended purpose of the devices concerned as they are covered by the UK MDR).

- We confirm that the **Otoport** medical devices we supply UK are compliant with the applicable requirements of UK MDR 2002.

In addition, these **Otoport** 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+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 60601-2-40:2019 (IEC 60601-2-40:2016); 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 60645-7:2010, IEC (2009); 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:

Otoport 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 (Cr6+- 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 **Otoport** do not contain phthalates.

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

- 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 Materials Derived from Animal Sources. Otodynamics products are not made with Natural Rubber Latex.
- 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.

Otoport product packaging is reusable. The **Otoport** medical device/ accessories is not supplied sterile or intended to be sterilized by the user. It is recommended that probe Ear Tips, Electrodes and Ear Cups are for single PATIENT use only.

Otoport System Items:

The Ear probes and the below items are part of the Otoport device system- together they are a class IIa medical device. Charging Cradle; Docking Station; Printer Pack/ Spares; Charger; UGS, UGD and XGD/ XPD Ear Probes/ Spares (Body/ Lid & Coupler Tubes, Tip Holders, Filters), Probe Ear Tips; Probe Pouch; Probe Cable Clip; Test Cavity; Infection Control Sleeves; Download Cable; Carry Case; Stand/ Crib Hook; Electrode Cables/ Electrodes; Ear Cups; ABR BINAURAL; Otolink Software; Calibration Unit (dealers only). More details are provided in the product manual. Reference the "F-008-57 Otoport Technical, Clinical Description & Declaration – UK DoC attachment Rev001" attachment document to this UK DoC for the complete list of Otoport items.

Authorised signatory: person responsible for regulatory compliance. **Place of Issue:** Otodynamics Ltd, Hatfield, Herts, UK.

Anastasios Parasiris	Product Quality Assurance & Regulatory Assurance Manager	Anastasios Parasiris	01/02/2024
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