MANUFACTURER'S EU DECLARATION OF CONFORMITY- DoC - Otoport
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 Otoport product (s) covered in this document are in conformance with the MDD/ EU MDR requirements as amended.

Medical device(s): **Otoport** Handheld Otoacoustic Emission- **OAE** Analyser System & Auditory Brainstem Response- **ABR** System for use with Otoport in hearing screening for the early identification of hearing loss.

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

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

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

European 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	EUDAMED DI*	Basic UDI-DI** (GS1 Global Model Number- GMN)
OTOPORT OAE				
OTOPORT ADVANCE	ADV-S	05060396170119	B-05060396170119	506039617OTOPORTVJ
OTOPORT FLEXI	FLX-S	05060396171208	B-05060396171208	
OTOPORT TE SCREENER	OS-ST	05060396171055	B-05060396171055	
OTOPORT LITE DP	LTC-SD	05060396170027	B-05060396170027	
OTOPORT LITE TE	LTC-ST	05060396170003	B-05060396170003	
OTOPORT NHSP OAE	NHSP-OS-ST	05060396171093	B-05060396171093	
OTOPORT OTOCHECK OAE				
OTOCHECK LE TE	LE-ST	05060396170171	B-05060396170171	506039617OTOPORTVJ
OTOCHECK LE DP	LE-SD	05060396170188	B-05060396170188	
OTOPORT OAE+ABR				
OTOPORT ADVANCE + ABR	ADV-S+ABR	05060396170126	B-05060396170126	506039617OTOPORTVJ
OTOPORT FLEXI + ABR	FLX-S +ABR	05060396171215	B-05060396171215	
OTOPORT TE SCREENER + ABR	OS-ST+ABR	05060396171062	B-05060396171062	
OTOPORT LITE DP + ABR	LTC-SD+ABR	05060396170034	B-05060396170034	
OTOPORT LITE TE + ABR	LTC-ST+ABR	05060396170010	B-05060396170010	
OTOPORT NHSP OAE+ABR SCREENER	NHSP-OS-ST+ABR	05060396171109	B-05060396171109	
OTOPORT ABR				
OTOPORT LITE ABR SCREENER	LTC-ABR	05060396170133	B-05060396170133	506039617OTOPORTVJ
OTOPORT NHSP ABR SCREENER	NHSP-OS-ABR	05060396171086	B-05060396171086	

Notes: ABR requirements are met by the **Otoport+**ABR system.
*: 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-008-38,REV003.2; 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 Otoport 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 Otoport) 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 **Otoport** OAE/ ABR device and Otolink 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 Otoport medical devices we supply EU are compliant with the applicable requirements of MDR 2017/745/EU. The Otoport 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 Otoport MDR certification is submitted to SGS NB1639: "REV10_LPMDREG1010 Product Information Questionnaire Rev10_V1_Otoport signed".
  - The current SGS EU MDR contract is "Otodynamics_GBPC_7309_EUMDR Proposal_signed_2023-11-28T11-28-00Z".

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.

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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 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.

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.
- 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.

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 & XGD 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-008-56 Otoport Technical, Clinical Description & Declaration – EU DoC attachment Rev001" attachment document to this EU DoC for the complete list of Otoport 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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