

## MANUFACTURER'S DECLARATION OF CONFORMITY- DoC -OtoNova 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.  
**Medical device(s):** **OtoNova** Otoacoustic Emission- OAE and Auditory Brainstem Response- **ABR** Analyser System for Use in the Analysis and Diagnosis of Hearing Loss with Nova- Link Software for Screening, Diagnosis and Data Management.

**Classification:** **Class IIa** under rules 5 & 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 **OtoNova** medical device with Nova-Link Software- S/W Screening & Clinical Application Variants (The OtoNova device product name and related GTIN-14: 05060396171123 are shown on the device label)

Variant Names	Variant Code	UDI- DI (GTIN-14), GS1	Basic UDI-DI/ EUDAMED DI
<b>OtoNova</b> Screener*	NOVA-SCR-TE	05060396171543	B-05060396171543
	NOVA-SCR-DP	05060396171550	B-05060396171550
	NOVA-SCR-ABR	05060396171567	B-05060396171567
	NOVA-SCR-DPTE	05060396171574	B-05060396171574
	NOVA-SCR-TE+ABR	05060396171581	B-05060396171581
	NOVA-SCR-DP+ABR	05060396171598	B-05060396171598
	NOVA-SCR-DPTE+ABR	05060396171604	B-05060396171604
<b>OtoNova</b> Clinical	NOVA-CLN-DPTE +ABR	05060396171628	B-05060396171628

**Note:** OtoNova with Nova-Link software is capable of performing three complementary hearing tests types, TE (Transient Evoked Oto-Acoustic Emissions)); DP (Distortion Product Oto-Acoustic Emissions); and ABR (Auditory Brainstem Response).

*\*For the OtoNova Screener variant, the variant code describes the specific configuration of these Test Types the customer has selected, controlled by a software license. Further information ref INF191-91-1*

**European Union  
Authorized Representative  
AR**



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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, 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 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 was valid from 14 May 2021 until 02 August 2023 (Expired).

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

Otodynamics products/ services are in compliance with the EU MDR and other regulatory region requirements 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 OtoNova products per the requirements of

- [MDCG-2020-3\_Rev1, May 2023]- Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD, and current; and EU MDR and other regulations.

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 OtoNova) 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 22 August, 2023 until 02 August 2026.

**Approved Body- AB:** SGS United Kingdom Ltd, AB 0120, Rossmore Business Park Ellesmere Port, Cheshire, CH65 3EN, UK.

### Regulations/ Standards applied:

The **OtoNova** 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 and in consideration of new Regulation (EU) 2017/745 of 5 April 2017 on medical devices (taking account of the intended purpose of the devices concerned).

- **We confirm that the OtoNova medical devices we supply EU are compliant with the applicable requirements of MDR 2017/745/EU. The OtoNova 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 OtoNova MDR certification is submitted to SGS NB1639: "REV10\_LPMREG1010 Product Information Questionnaire Rev10\_V1\_OtoNova signed" and now expecting the SGS NB 1639 MDR contract.
  - The current SGS MDD contract is "OTODYNAMICS LTD\_GBPC\_05615\_GBPC\_5335\_ContractOffer D8 signed\_2023-03-14".

In addition, these **OtoNova** 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 and "Packaging Directive" 94/62/EC.

### Declared Conformance to the following standards:

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**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:

**OtoNova** products do not contain any of the restricted substances in concentrations and 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 **OtoNova** 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.

**OtoNova** product packaging is reusable. The **OtoNova** medical device/ system 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.

#### OtoNova System Items:

UPS, UPD & XPD Probes/ Spares (Body/ Lid & Coupler Tubes, Tip Holders, Elastomers), Probe Ear Tips; Probe Pouch; Probe Cable Clip; Test Cavity; Charger Power Supply; Wireless Charger; Electrode Cables/ Electrodes; Ear Cups; ABR Starter Kit; Otolink Software; Calibration Unit; Device Hook, Crib/Bassinette; Carry Case; **OTONOVA** ABR BINAURAL; **OTONOVA** Tablet. More details are provided in the product manual.

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

Anastasios Parasiris

Name

Product Quality Assurance Manager

Position

Anastasios Parasiris

Signature

23/08/2023

(DD/MM/YYYY)

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