

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, Herts
AL10 8BB, UK

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: (10228) _ Audiometers;
(17601) _ Auditory Function Screening Devices;
(16303) _ Audiometric Evoked-Potential Units

CND Structure Z121401: *Audiometers*;
Z12149001: *Auditory Function Screening Devices*;
Z121403: *Evoked Potential Audiometry Instruments*; Z12140302: *Evoked Potential Audiometry Units*; Z12140301: *Evoked Potential Audiometry Integrated Systems*

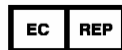
Scope of application: Current **OtoNova** medical device with Nova-Link Software- S/W Screening & Clinical Application Variants (The **OtoNova** product name is on the device label)

Variant Names	Variant Code	UDI (GTIN-13)
OtoNova Screener*	NOVA-SCR-TE	5060396171543
	NOVA-SCR-DP	5060396171550
	NOVA-SCR-ABR	5060396171567
	NOVA-SCR-DPTE	5060396171574
	NOVA-SCR-TE+ABR	5060396171581
	NOVA-SCR-DP+ABR	5060396171598
	NOVA-SCR-DPTE+ABR	5060396171604
OtoNova Clinical	NOVA-CLN-DPTE +ABR	5060396171628

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 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 **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 02 August 2023.**

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:

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; IEC 60601-2-40:2016 (EN 60601-2-40:2019); 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 60645-7:2010; EN ISO 10993-1:2020; EN IEC 63000:2018; 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:

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.

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- 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:

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

Anastasios Parasiris
Name

Product Quality Assurance Manager
Position



Signature

25/05/2021
(DD/MM/YYYY)

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