

To whom it may concern

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Staefa (Switzerland), August 2020 / Glenn Borrett Senior Regulatory Affairs Manager

# RoHS, REACH and WEEE Declaration of Conformity Hearing Instrument Systems RoHS and China RoHS Compliance Declaration

We, the undersigned, hereby declare, under our sole responsibility that the products listed in document QDL-15 (non-wireless) QDL-13 (wireless), QDL-123 and QDL-291, including all related accessories, introduced on the market from 22 July 2014 onwards conform with all the essential requirements of the Directive 2011/65/EU of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (in future text RoHS2 Directive) and are produced under a quality scheme at least in conformity with ISO 9001, ISO 13485 and ISO 14001.

For the products listed above the Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (RoHS 3 Directive) becomes effective from 22 July 2019 for non- Medical Devices and from 22 July 2021\* for Medical Devices. The restriction of DEHP, BBP, DBP and DIBP do not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices placed on the market before 22 July 2021.

RoHS Restricted Substance	Allowable Limit
Cadmium and its compounds	100 ppm (0.01 weight %)
Mercury and its compounds	1000 ppm (0.1 weight %)
Hexavalent chromium and its compounds	1000 ppm (0.1 weight %)
Lead and its compounds	1000 ppm (0.1 weight %)
Polybrominated biphenyls (PBB)	1000 ppm (0.1 weight %)
Polybrominated diphenyl ethers (PBDE)	1000 ppm (0.1 weight %)
Bis(2-ethylhexyl) phthalate (DEHP)*	1000 ppm (0.1 weight %)
Butyl benzyl phthalate (BBP)*	1000 ppm (0.1 weight %)
Dibutyl phthalate (DBP)*	1000 ppm (0.1 weight %)
Diisobutyl phthalate (DIBP)*	1000 ppm (0.1 weight %)

The mentioned products QDL-15, QDL-13, QDL-123 and QDL-291 conform to the requirements of "Measures for the Administration of the Restricted Use of the Hazardous Substances Contained in Electrical and Electronic Products", issued on January 6, 2016 by the Ministry of Industry and Information Technology of the People's Republic of China ("China ROHS").

The following exemptions listed in the RoHS2 Directive may be applicable to individual parts of individual products and/or accessories:



a. b.	2011/65/EU Annex III: 6(c) 2011/65/EU Annex III: 8(b)	Copper alloy containing up to 4 % lead by weight Cadmium and its compounds in electrical contacts
c.	2011/65/EU Annex III: 15	Lead in solders to complete a viable electrical connection
	2011,00,2011	between semiconductor die and carrier within integrated circuit flip chip packages
d.	2011/65/EU Annex III: 30	Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more
e.	2011/65/EU Annex III: 33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers
_f	2011/65/EU Annex III: 34	Lead in cermet-based trimmer potentiometer elements

The applicable harmonised standard describing the documentary evidence of conformity with RoHS2 is EN 50581:2012, superseded by EN IEC 63000:2018.

## **REACH Compliance Declaration**

We hereby also declare, under our sole responsibility, that the products listed in documents QDL-15, QDL-13, QDL-123 and QDL-291, including all related accessories manufactured by Sonova AG fully comply with the related requirements of European Union Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as well as with the reporting requirements outlined by the Article 9(i) of the Directive 2008/98/EC of the European Parliament and of the council of 19 November 2008 on waste and repealing certain Directives which apply from 5. January 2021.

Sonova AG will meet all applicable REACH requirements and is committed to providing our customers with information about the chemicals in our components or products. Sonova AG works cohesively with suppliers in the industry to ensure that Sonova AG products comply with REACH.

Under the structure of the REACH regulation, Sonova AG is a manufacturer of "ARTICLES" to our EU customers. We do not manufacture "substances" or "preparations" and our articles do not involve the "intentional release of substances". Accordingly, we foresee no registration or pre-registration or Authorization requirement for the products we supplied.

Sonova AG and its suppliers have taken the necessary action to meet the requirements of REACH to ensure that Sonova AG Products can continue to be supplied in the EEA.

#### Sonova AG REACH Declaration related to substances in articles:

In accordance with REACH Regulation Article 33 (Communication of information on substances in articles) the table below indicates which substance(s) of very high concern (SVHC) may be present in Sonova AG products above the threshold level of 0.1% by weight of the article. Based on our current knowledge and current supplier information, no other SVHC are present in our components or products.

Substance of Very High Concern (SVHC)	CAS Number	Comments
DEHP, bis(2-ethyl(hexyl)phthalate)	117-81-7	This substance may be present in separately sold PVC tubing and cables or in components made of PVC within the product; this substance may be present in decorative parts
1,3-propanesultone	1120-71-4	This substance may be present in Li batteries used in any of the Sonova brand products.
Lead titanium trioxide	12060-00-3	This substance may be present in dielectric layers of microphones in any of the Sonova brand products.

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Lead

7439-92-1

The substance may be present in in electrical contacts as an alloying element in copper alloys and electronic ceramic parts

# **WEEE Compliance Declaration**

We hereby also declare, under our sole responsibility, that the products listed in documents QDL-15 QDL-13 QDL-123 and QDL-291 including all related accessories manufactured by Sonova AG fully comply with the related requirements of the European Community Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

All products manufactured by Sonova AG that are subject to the WEEE Directive are compliant with the WEEE marking requirements as indicated and in accordance with EN50419.

The WEEE symbol requires that the product must not be disposed of with normal household waste. Such marked waste equipment must be disposed of by arranging to return to a designated collection point for the recycling of waste electrical and electronic equipment.

This declaration of conformity is valid from the date of signature until it is explicitly revoked

Place: Staefa, Date: (3. Aug 2020)

Group Vice President

Research & Development

Place: Staefa, Date: 13 Any 2020

G.Borrett

Senior Regulatory Affairs Manager

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### **Approvals**

Level	<u>Actor</u>	<u>Job Title</u>	Sign-off Date	Sign-off By
1	Nataya Jaiman	TQM Regulatory Affairs Assistant	13-Aug-2020	11NJAIMAN
2	Glenn Borrett	Senior Manager Regulatory	13-Aug-2020	11GBORRETT
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All

#### **Revision Notes**

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