

To whom it may concern

Stäfa (Switzerland), March 2022/ G.Borrett, Senior Manager Regulatory Affairs

Product Equality Declaration

We, Sonova AG, hereby declare under our own responsibility that the products listed below as “Hardware Equivalent Products - Phonak Brand” are in all relevant parts and hardware construction identical to the corresponding product identified as “Products with basis Hardware”. The following standards and/or technical regulations and corresponding test reports fully apply accordingly:

Standards Phonak brands
<p>Hearing Aid standards: ACOUSTIC: IEC 60118-0-1-2-6 and NSH 7.0 (including Annex A); EMC: IEC 6011 8-13; EMC immunity: ANSI C63.19 Degrees of protection provided by enclosures (IP code): IEC 60529:1989-11+A1:1999; EN 60529:1991-10 (incl. Corrigendum: 1993-05)+A1:2000-02</p> <p>Europe: HEALTH & SAFETY: IEC/EN 60601-1, IEC/EN 60601-2-66, IEC/EN 62368-1; IEC/EN 62133; IEC/EN 62479; EMC: IEC/EN 60601-1-2; EN 301489-1,-3,-17; SPECTRUM: EN 300328; EN ETSI 303417; REACH; RoHS-III</p> <p>USA: 47 CFR Part 15(B), Part 15(C): 15.249, Part 2: 2.1091, 2.1093; Canada: RSS-Gen, ICES-003, RSS-210, RSS-102; RSS-247 ; RSS-216 Japan: ARIB 166, Ordinance regulating Radio Equipment (2005-08) Ar12 item 19</p>

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The only difference between the basis product and the equivalent ones is a set of different audiological features per performance level and marketing product name. The difference between devices indicated as “left” and “right” are minor changes to plastic parts only. There will be no impact on the wireless characteristics.

Products with basis Hardware (tested representative model)	Hardware Equivalent Products – Phonak Brand
Phonak Slim P90-R left HW version: 050-0850-xx (left) SW version: Target 7.2 FW version: 067-1462	Phonak Slim P90-R right (with S/M/P/MAV receivers) HW version: 050-0851-xx (right) SW version: Target 7.2 FW version: 067-1462
	Phonak Slim P70-R left Phonak Slim P70-R right (with S/M/P/MAV receivers) HW version: 050-0848-xx (left),050-0849-xx (right) SW version: Target 7.2 FW version: 067-1463
	Phonak Slim P50-R left Phonak Slim P50-R right (with S/M/P/MAV receivers) HW version:050-1009-xx (left),050-1010-xx (right) SW version: Target 7.2 FW version: 067-1470
	Phonak Slim P30-R left Phonak Slim P30-R right (with S/M/P/MAV receivers) HW version:050-1007-xx (left),050-1008-xx (right) SW version: Target 7.2 FW version: 067-1471
	Phonak Slim P-R Trial left Phonak Slim P-R Trial right (with S/M/P/MAV receivers) HW version:050-0853-2A (left),050-0854-2A (right) SW version: Target 7.2 FW version: 067-1462

Furthermore, this document declares that the following devices, which are non-Phonak branded, differ from the model under test “Phonak Slim P90-R left” mainly with respect to color, naming and some minor changes to top and bottom housing (plastic parts only), that are not considered to be significant enough to cause any measurable effect for electrical safety or RF performance according to the list of standards indicated below.

Standards non-Phonak brands
Hearing Aid standards: Degrees of protection provided by enclosures (IP code): IEC 60529:1989-11+A1:1999; EN 60529:1991-10 (incl. Corrigendum: 1993-05)+A1:2000-02
Europe: HEALTH & SAFETY: IEC/EN 60601-1, IEC/EN 60601-2-66, IEC/EN 62368-1; IEC/EN 62133; IEC/EN 62479; EMC: IEC/EN 60601-1-2; EN 301489-1,-3,-17; SPECTRUM: EN 300328; EN ETSI 303417; REACH; RoHS-III
USA: 47 CFR Part 15(B), Part 15(C): 15.249, Part 2: 2.1091, 2.1093; Canada: RSS-Gen, ICES-003, RSS-210, RSS-102; RSS-247 ; RSS-216 Japan: ARIB 166, Ordinance regulating Radio Equipment (2005-08) Ar12 item 19

Unitron	Vista	HANSATON	Specsavers
Moxi B9-RS	Vista B9-RS	AQ sound ST 9-S	Advance 871-RS
Moxi B7-RS	Vista B7-RS	AQ sound ST 7-S	Advance 771-RS
Moxi B5-RS	Vista B5-RS	AQ sound ST 5-S	Advance 671-RS
Moxi B3-RS	Vista B3-RS	AQ sound ST 3-S	Advance 471-RS
Moxi B1-RS	Vista B1-RS	AQ sound ST 1-S	Advance 271-RS
Moxi B-RS FLEX:TRIAL	Vista B-RS trial Vista B-RS Select	AQ sound ST S myChoice	

where xx – means color identification

Staefa, 31 March 2022

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Rev.: 2	
Title: DoE Phonak Slim P-R	
Process: Innovation Management	
Owner: 11TKIEFER Thomas Kiefer	

Attributes

<u>Attribute Type</u>	<u>Value</u>	<u>Description</u>
Affected Site	1100	Stafa (CH)
Project	SlimDesign	
Project Phase	Design Output	

Approvals

<u>Level</u>	<u>Actor</u>	<u>Job Title</u>	<u>Sign-off Date</u>	<u>Sign-off By</u>
1	Nataya Jaiman	TQM Regulatory Affairs Assistant	31-Mar-2022	11NJAIMAN
2	Glenn Borrett	Senior Manager Regulatory Affairs	04-Apr-2022	11GBORRETT
2	Blathnaid Feldman	Director Quality Management & Regulatory Affairs	01-Apr-2022	11BFELDMAN

Revision Notes

<u>Access Activity</u>	<u>Note</u>	<u>Accessed By</u>	<u>Accessed Date</u>
Remark	Added a phrase to the Phonak Slim DoE to justify the equality among the different performance levels	11NJAIMAN	31-Mar-2022