

To whom it may concern

Stäfa (Switzerland), December 2021 / Glenn 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” 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
ACOUSTIC: EN 60118-0-1-2-6, NSH 7th edition, NHS 7.0 Annex A, ANSI C63.19 EMC: IEC/EN 60118-13 Europe: Health and Safety: IEC/EN 60601-1, IEC/EN 60601-2-66, IEC/EN 62304, IEC/EN 62479; EMC: IEC/EN 60601-1-2; EN 301489-1,-3,-17; REACH; RoHS III SPECTRUM: EN 300 328; EN 300 422-4 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; Japan: ARIB 166, Ordinance regulating Radio Equipment (2005-08) Ar12 item 19

The only difference between the listed equivalent and corresponding basis models is the model name, a different set of audiological features per performance level and new corresponding fitting software due to marketing purposes.

Products with basis Hardware (tested representative model)	Hardware Equivalent Products
Phonak Virto P90-Titanium (Receiver: M / P / SP) HW version: 063-0001-01 FW version: 068-1408 SW version: Target 7	Phonak Virto P70-Titanium (Receiver: M / P / SP) HW version: 063-0005-01 FW version: 068-1409 SW version: Target 7
	ampli-mini I 5 P Ti NWL (Receiver: M / P / SP) HW version: 063-0524-01 FW version: 068-1408 SW version: Target 7
	ampli-mini I 4 P Ti NWL (Receiver: M / P / SP) HW version: 063-0525-01 FW version: 068-1409 SW version: Target 7
Phonak Virto P90-10 NW O (Receiver: M / P / SP) HW version: 063-0002-01 FW version: 068-1404 SW version: Target 7	Phonak Virto P70-10 NW O (Receiver: M / P / SP) HW version: 063-0006-01 FW version: 068-1405 SW version: Target 7

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	Phonak Virto P50-10 NW O (Receiver: M / P / SP) HW version: 063-0508-01 FW version: 068-1406 SW version: Target 7
	Phonak Virto P30-10 NW O (Receiver: M / P / SP) HW version: 063-0511-01 FW version: 068-1407 SW version: Target 7
	Phonak Brio 5 I-10 NW O (Receiver: M / P / SP) HW version: 063-0514-01 FW version: 068-1404 SW version: Target 7
	ampli-mini I 5 P 10 NWL (Receiver: M / P / SP) HW version: 063-0516-01 FW version: 068-1404 SW version: Target 7
	ampli-mini I 4 P 10 NWL (Receiver: M / P / SP) HW version: 063-0517-01 FW version: 068-1405 SW version: Target 7
	ampli-mini I 3 P 10 NWL (Receiver: M / P / SP) HW version: 063-0518-01 FW version: 068-1406 SW version: Target 7
	ampli-mini I 2 P 10 NWL (Receiver: M / P / SP) HW version: 063-0519-01 FW version: 068-1407 SW version: Target 7
Phonak Virto P90-312 NW O (Receiver: M / P / SP) HW version: 063-0003-01 FW version: 068-1400 SW version: Target 7	Phonak Virto P70-312 NW O (Receiver: M / P / SP) HW version: 063-0007-01 FW version: 068-1401 SW version: Target 7
	Phonak Virto P50-312 NW O (Receiver: M / P / SP) HW version: 063-0509-01 FW version: 068-1402 SW version: Target 7
	Phonak Virto P30-312 NW O (Receiver: M / P / SP) HW version: 063-0512-01 FW version: 068-1403 SW version: Target 7
Phonak Virto P90-312 (Receiver: M / P / SP / UP) HW version: 063-0004-01 FW version: 068-1430 SW version: Target 7	Phonak Virto P70-312 (Receiver: M / P / SP / UP) HW version: 063-0008-01 FW version: 068-1431 SW version: Target 7
	Phonak Virto P50-312 (Receiver: M / P / SP / UP) HW version: 063-0510-01 FW version: 068-1432 SW version: Target 7

	Phonak Virto P30-312 (Receiver: M / P / SP / UP) HW version: 063-0513-01 FW version: 068-1433 SW version: Target 7
	Phonak Brio 5 I-312 (Receiver: M / P / SP / UP) HW version: 063-0515-01 FW version: 068-1430 SW version: Target 7
	ampli-mini I 5 P 312 WL (Receiver: M / P / SP / UP) HW version: 063-0520-01 FW version: 068-1430 SW version: Target 7
	ampli-mini I 4 P 312 WL (Receiver: M / P / SP / UP) HW version: 063-0521-01 FW version: 068-1431 SW version: Target 7
	ampli-mini I 3 P 312 WL (Receiver: M / P / SP / UP) HW version: 063-0522-01 FW version: 068-1432 SW version: Target 7
	ampli-mini I 2 P 312 WL (Receiver: M / P / SP / UP) HW version: 063-0523-01 FW version: 068-1433 SW version: Target 7

Staefa, 17.12.2021

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Type:	PDL	Status:	CURRENT
Document No.:	PDL-6548	Effective Date:	21-Dec-2021
Rev.:	2		
Title:	DoE CTC/DEKRA Mozart ITE (Virto P, ampli-mini, Brio 5 ITE)		
Process:	Regulatory Affairs		
Owner:	53AGOIA Andrei Goia		

Attributes

Attribute Type	Value	Description
Affected Site	1100	Stafa (CH)
Project	Mozart ITE Product	
Project Phase	User Needs	

Approvals

Level	Actor	Job Title	Sign-off Date	Sign-off By
1	Nataya Jaiman	TQM Regulatory Affairs Assistant	21-Dec-2021	99SBENSALEM
2	Glenn Borrett	Senior Manager Regulatory Affairs	21-Dec-2021	11GBORRETT

Revision Notes

Access Activity	Note	Accessed By	Accessed Date
Remark	Safety, RF and other relevant standards added to accommodate for DEKRA testing. Names of the devices adjusted due to changes in the project	11KBELFORT	17-Dec-2021