

To whom it may concern

Stäfa (Switzerland), January 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” are in all relevant parts and hardware construction identical to the corresponding product identified as “Products with basis Hardware”. The following standards and/or

Standards
Hearing Aid standards: ACOUSTIC: IEC 60118-0,-1,-2,-6 and NSH 7.0 (including Annex A); EMC: IEC 60118-13; 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
Europe: HEALTH & SAFETY: IEC/EN 60601-1, IEC/EN 60601-2-66; IEC/EN 62133; IEC/EN 62479; EMC: IEC/EN 60601-1-2; EN 301489-1,-3,-17; SPECTRUM: EN 300328; EN 300422-4; 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.
Japan: ARIB T66, Ordinance regulating Radio Equipment (2005-08) Ar12 item 19

technical regulations and corresponding test reports fully apply accordingly:

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 Audéo P90-R Fit (with Sensor M/P) HW version : 050-0870-xx SW version: Target 7 FW version : 067-1466	Phonak Audéo P70-R Fit (with Sensor M/P) HW version : 050-0869-xx SW version: Target 7 FW version : 067-1467
	Phonak Audéo P-R Fit Trial (with Sensor M/P) HW version : 050-0873-P6 SW version: Target 7 FW version : 067-1466
	Phonak Brio 5 Move (with Sensor M/P) HW version : 050-0870-xx56 SW version: Target 8 FW version : 067-1466
	Phonak Brio 5 Move Demo (with Sensor M/P) HW version : 050-0870-P657 SW version: Target 8 FW version : 067-1466

where xx – means color identification

Place and date

Staefa, 28 January 2022



B.Feldman
Senior Director Global Quality Management

Staefa, 28 January 2022



G.Borrett
Senior Regulatory Affairs Manager

Type:	PDL	Status:	CURRENT
Document No.:	PDL-8685	Effective Date:	28-Jan-2022
Rev.:	2		
Title:	Product Equality Declaration Audéo Fit		
Process:	Regulatory Affairs		
Owner:	11GBORRETT Glenn Borrett		

Attributes

Attribute Type	Value	Description
Affected Site	1100	Stafa (CH)
Project	Mozart Floyer Product	
Project Phase	Design Process	

Reference

Document No.	Title	Content Type	Relation
PDL-10004 [1]	Audeo P Fit Product Equality Declaration incl Private label	DOCUMENT	Related

Approvals

Level	Actor	Job Title	Sign-off Date	Sign-off By
1	Nataya Jaiman	TQM Regulatory Affairs Assistant	28-Jan-2022	11NJAIMAN
2	Glenn Borrett	Director Regulatory Affairs	28-Jan-2022	11GBORRETT

Revision Notes

Access Activity	Note	Accessed By	Accessed Date
Remark	Phonak Brio 5 Move Demo added	11NJAIMAN	28-Jan-2022