

DocuSigned by:
Julia SZCZESNIAK
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To whom it may concern

Stäfa (Switzerland), May 2021 / G.Borrett Senior Manager Regulatory Affairs

Declaration of Conformity

Hearing Instrument Systems

We, the undersigned, hereby declare under our sole responsibility that the medical devices (class 2a) listed on pages 2 to 6, conform to the Medical Device Directive 93/42/EEC. Inclusive its related Fitting Software (GMDN 60211): Phonak iPFG 2.6b (also named Argosy iPFG 2.6), 2.6c/2.6d/2.6e; Phonak Target 3.0/3.1/3.2/3.3/4.0/4.1/4.2/4.3/5.0/5.1,5.2,5.3,5.4,6.0,6.1,6.2,7.0,7.1(GMDN 60211) Argosy Target 3.3 and accessories.

Authorized Representative : Sonova Deutschland GmbH, Max-Eyth-Straße 20, 70736 Fellbach, Germany.

These products are in conformity with the following standards and/or other normative documents:

ACOUSTIC: EN/IEC 60118-0,-1,-2,-6; NSH 7.0;
EMC: EN/IEC 60118-13; IEC/EN 60601-1-2;
HEALTH & SAFETY: EN/IEC 60601-1;
Biocompatibility: ISO 10993-1; MD Software: IEC 62304;

This declaration is supported by:

Certificate of approval No.: 31857 to the quality standard SN EN ISO 9001 and
Certificate No.: 30379 to the quality standard SN EN ISO 13485 issued by GMED and
EC Certificate No.: 30380 acc. to the ANNEX II excl #4 DIRECTIVE 93/42/EEC issued by GMED
(Notified Body No.: 0459).

Place and Date:

Stäfa, 18 May 2021



Laurent Vicari
Director Quality Management & Regulatory Affairs

Stäfa, 18 May 2021



Glenn Borrett
Senior Manager Regulatory Affairs
Operations

Model/Type		Analog Signal Proc.	Digital Programmable	Digital Signal Proc.	Remote Control	FM Input [AUX]	Easy Phone	GMDN BTE (34671)	GMDN RIC (CRT) (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Phonak Virto V	Phonak Virto V90-nano (Option: M)		X	X							X
	Phonak Virto V70-nano (Option: M)		X	X							X
	Phonak Virto V50-nano (Option: M)		X	X							X
	Phonak Virto V90-10 NW O (Options: M, P, SP)		X	X		X					X
	Phonak Virto V70-10 NW O (Options: M, P, SP)		X	X		X					X
	Phonak Virto V50-10 NW O (Options: M, P, SP)		X	X		X					X
	Phonak Virto V30-10 NW O (Options: M, P, SP)		X	X		X					X
Lyric	Lyric2 (Options: XS, S, M, L, XL)				X						X
	Lyric3 (Options: XXS, XS, S, M, L, XL, XXL)				X						X
Phonak Audéo Q	Phonak Audéo Q90-10 Also named Phonak Brio R-10		X	X					X		
	Phonak Audéo Q70-10		X	X					X		
	Phonak Audéo Q50-10		X	X					X		
	Phonak Audéo Q30-10		X	X					X		
Naída S	Naída S I SP Also named Lapperre CS 3010 Also named Argosy Alize 100 SP		X	X		X		X			
	Naída S I UP Also named Lapperre CS 3011 Also named Argosy Alize 100 UP		X	X		X		X			
Phonak Virto Q	Phonak Virto Q90-nano NWO Also named Lapperre Pro I 921 Also named Phonak Brio I-N NW O		X	X							X
	Phonak Virto Q90-10 NW O Also named Lapperre Pro I 922 Also named Phonak Brio I-10 NW O		X	X	X		X				X
	Phonak Virto Q90-312 NW Also named Phonak Brio I-312 NW		X	X	X		X			X	
	Phonak Virto Q70-nano NWO Also named Lapperre Pro I 721		X	X							X
	Phonak Virto Q70-10 NW O Also named Lapperre Pro I 722		X	X	X		X				X
	Phonak Virto Q70-312 NW		X	X	X		X			X	
	Phonak Virto Q50-nano NWO Also named Lapperre Pro I 521		X	X							X

Model/Type		Analog Signal Proc.	Digital Programmable	Digital Signal Proc.	Remote Control	FM Input [AUX]	Easy Phone	GMDN BTE (34671)	GMDN RIC (CRT) (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)	
	Phonak Virto Q50-10 NW O Also named Lapperre Pro I 522		X	X	X		X				X	
	Phonak Virto Q50-312 NW		X	X	X		X			X		
	Phonak Virto Q30-10 NW O Also named Lapperre Pro I 322		X	X	X		X				X	
	Phonak Virto Q30-312 NW		X	X	X		X			X		
Phonak Baseo Q	Phonak Baseo Q15-UP		X	X		X		X				
	Phonak Baseo Q15-M Also named Argosy Bossa 15-M		X	X		X		X				
	Phonak Baseo Q15-P		X	X		X		X				
	Phonak Baseo Q15-SP Also named Argosy Bossa 15-SP		X	X		X		X				
	Phonak Baseo Q10-M Also named Argosy Bossa 10-M		X	X		X		X				
	Phonak Baseo Q10-SP Also named Argosy Bossa 10-SP		X	X		X		X				
	Phonak Baseo Q5-M		X	X				X				
	Phonak Baseo Q5-SP		X	X				X				
	Phonak Tao Q	Phonak Tao Q15-10 NW O Also named Argosy Theo 15-10 Petit		X	X							X
Phonak Tao Q15-312 NW Also named Argosy Theo 15-312 Petit			X	X						X		
Phonak Tao Q15-13 NW Also named Argosy Theo 15-13 Petit			X	X						X		
Phonak Tao Q10-10 NW O Also named Argosy Theo 10-10 Petit			X	X							X	
Phonak Tao Q10-312 NW O Also named Argosy Theo 10-312 Petit			X	X						X		
Phonak Tao Q10-13 NW			X	X						X		
Phonak Dalia		Phonak Dalia SP Also named Lapperre CS 314		X	X		X		X			
		Phonak Dalia microP Also named Lapperre PCA 313 Also named Argosy Dixie microP		X	X		X		X			
	Phonak Dalia M H2O Also named Lapperre PCA 312 Hydro Also named Argosy Dixie M H2O		X	X		X		X				
	Phonak Dalia microM Also named Lapperre PCA 312		X	X				X				
	Phonak Dalia 10 Petite (Options: M, P, SP) Also named Lapperre CIC 315 Also named Argosy Dixie 10 Petit		X	X							X	

Model/Type	Analog Signal Proc.	Digital Programmable	Digital Signal Proc.	Remote Control	FM Input [AUX]	Easy Phone	GMDN BTE (34671)	GMDN RIC (CRT) (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Phonak Dalia 312 UZ Petite (Options: M, P, SP, UP) Also named Lapperre ITC 317 Also named Argosy Dixie 312 UZ Petit		X	X						X	
Phonak Dalia 13 UZ Petite (Options: M, P, SP, UP) Also named Lapperre ITC 318		X	X						X	

Phonak Nathos S+

Phonak Nathos S+ micro		X	X	X	X		X			
Phonak Nathos S+ M		X	X	X	X		X			

Phonak Solana	Model/Type	Analog Signal Proc.	Digital Programmable	Digital Signal Proc.	Remote Control	FM Input [AUX]	Easy Phone	GMDN BTE (34671)	GMDN RIC (CRT) (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Phonak Solana	Phonak Solana 10 Petite (option M, P, SP) also named Lapperre CIC 715 also named Argosy Salza 10 Petit		X	X							X
	Phonak Solana 312 Petite (option M, P, SP, UP) also named Lapperre ITC 716		X	X			X			X	
	Phonak Solana 312 UZ Petite (option M, P, SP) also named Lapperre ITC 717		X	X			X			X	
	Phonak Solana Petite		X	X				X			
	Phonak Solana nano also named Argosy Salza nano		X	X							X

Phonak Cassia	Model/Type	Analog Signal Proc.	Digital Programmable	Digital Signal Proc.	Remote Control	FM Input [AUX]	Easy Phone	GMDN BTE (34671)	GMDN RIC (CRT) (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Phonak Cassia	Phonak Cassia nano also named Argosy Clara nano		X	X							X
	Phonak Cassia 10 Petite (option M, P, SP) also named Lapperre CIC 515 also named Argosy Clara 10 Petit		X	X							X
	Phonak Cassia 312 Petite (option M, P, SP, UP) also named Lapperre ITC 516		X	X			X			X	
	Phonak Cassia 312 UZ Petite (option M, P, SP) also named Lapperre ITC 517		X	X			X			X	
	Phonak Cassia Petite		X	X			X	X			

Nathos	Nathos micro		X	X		X		X			
	Nathos M		X	X		X		X			

Model/Type		Analog Signal Proc.	Digital Programmable	Digital Signal Proc.	Remote Control	FM Input [AUX]	Easy Phone	GMDN BTE (34671)	GMDN RIC (CRT) (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Audéo	Audéo S MINI III also named Lapperre PCA 511		X	X					X		
	Audéo S MINI V also named Lapperre PCA 711		X	X					X		
	Audéo S MINI IX also named Lapperre PCA 911		X	X					X		
	Audéo S SMART I also named Lapperre PCA 310 also named Argosy iPCA 100		X	X					X		
Phonak Ambra	Phonak Ambra 10 Petite (option M, P, SP) also named Lapperre CIC 915		X	X	X		X				X
	Phonak Ambra 312 Petite (option M, P, SP, UP) also named Lapperre ITC 916		X	X	X		X			X	
	Phonak Ambra 312 UZ Petite (option M, P, SP) also named Lapperre ITC 917		X	X	X		X			X	
	Phonak Ambra Petite		X	X				X			
	Phonak Ambra nano		X	X							X
Naida	Naída I UP also named Argosy Alize I UP		X	X	X	X		X			
	Naída I SP also named Argosy Alize I SP		X	X	X	X		X			
Exélia Art	Exélia Art micro Petite also named Royal		X	X	X		X	X			
	Exélia Art CIC/MC P Petite		X	X	X		X				X
	Exélia Art CIC/MC Petite		X	X	X		X				X
	Exélia Art ITC/HS Petite		X	X	X		X				X
	Exélia Art ITC/HS VZ Petite		X	X	X		X				X
	Exélia Art ITC/HS P VZ Petite		X	X	X		X				X
Versáta Art	Versáta Art CIC/MC P Petite		X	X	X		X				X
	Versáta Art CIC/MC Petite		X	X	X		X				X
	Versáta Art ITC/HS P VZ Petite		X	X	X		X				X
	Versáta Art ITC/HS Petite		X	X	X		X				X
	Versáta Art ITC/HS VZ Petite		X	X	X		X				X
	Versáta Art micro Petite		X	X	X		X	X			
Certéna Art	Certéna Art CIC/MC P Petite		X	X	X		X				X
	Certéna Art CIC/MC Petite		X	X	X		X				X
	Certéna Art ITC/HS P dAZ Petite		X	X	X		X				X
	Certéna Art ITC/HS Petite		X	X	X		X				X
	Certéna Art ITC/HS dAZ Petite		X	X	X		X				X
	Certéna Art micro Petite		X	X	X		X	X			
A = Audéo MINI IX		X	X					X			


Model/Type

Analog Signal Proc.
 Digital Programmable
 Digital Signal Proc.
 Remote Control
 FM Input [AUX]
 Easy Phone
 GMDN BTE (34671)
 GMDN RIC (CRT) (47169)
 GMDN ITE (34672)
 GMDN ITC/CIC (41209)

	Audéo MINI V		X	X					X		
	Audéo MINI III		X	X					X		

Milo	Milo micro also named Argosy Cira micro		X	X		X		X			
	Milo SP also named Argosy Cira SP		X	X		X		X			
	Milo UP also named Argosy Cira UP		X	X		X		X			
	Milo Plus micro also named Argosy Cira Plus micro		X	X		X		X			
	Milo Plus SP also named Argosy Cira Plus SP		X	X		X		X			
	Milo Plus UP also named Argosy Cira Plus UP		X	X		X		X			
	Milo Plus CIC/MC also named Argosy Cira Plus CIC/MC		X	X							X
	Milo Plus ITC/HS dAZ also named Argosy Cira Plus ITC/HS dAZ		X	X							X
	Milo Plus FS dAZ also named Argosy Cira Plus FS dAZ		X	X						X	
	Milo Plus FS P dAZ		X	X						X	

OK!	OK! M also named Argosy Della M			X				X			
	OK! SP also named Argosy Della SP			X				X			
	OK! UP also named Argosy Della UP			X				X			
	OK! Plus M also named Argosy Della Plus M			X		X		X			
	OK! Plus SP also named Argosy Della Plus SP			X		X		X			
	OK! Plus UP also named Argosy Della Plus UP			X		X		X			

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