



LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits
June 16th, 2014 C. Schiffrer
 LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

Phonak AG

Laubisrütistrasse 28
 CH-8712 Stäfa
 Switzerland

Phone +41 58 928 01 01
 Fax +41 58 928 21 11

To whom it may concern

Stäfa (Switzerland), 10 June 2014 / *I* J. Itin, Director of Corp. TQM

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, Phonak iPFG 2.6b (also named Argosy iPFG 2.6), / 2.6c, Phonak Target 3.0/3.1/3.2/3.3, Argosy Target 3.3 and accessories.

Legal Manufacturer: **Phonak AG**
 Laubisrütistrasse 28,
 CH-8712 Stäfa, Switzerland

Manufacturing Sites: **Unitron Hearing (Suzhou) Co. Ltd.**
 No. 78 Qi Ming Road, Comprehensive Bonded Zone,
 Suzhou Industrial Park, Jiangsu Province, P.R. China

Phonak Operation Center Vietnam Co. Ltd.
 No. 29A VSIP Street 8, Vietnam Singapore Industrial Park
 Thuan An Town, Binh Duong Province, Vietnam

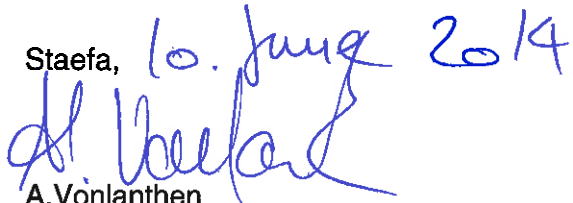
This declaration is supported by:

Certificate of approval No.: 7592 to quality standards SN EN ISO 9001 : 2008 and SN EN ISO 13485 : 2003 issued by LNE / G-Med and EC Certificate No.: 7591 ANNEX II excl #4 DIRECTIVE 93/42/EEC issued by LNE / G-Med (Notified Body No.: 0459).

Place and Date:

Stäfa, *10 June 2014*

 H. Mehl
 Group Vice President
 Operations

Stäfa, *10. June 2014*

 A. Vonlanthen
 Group Vice President
 Research & Development

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)
Lyric Lyric2 Options: XS, S, M, L, XL				X						X
Lyric3 Options: XS, S, M, L, XL				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		
Naida S Naida S I SP Also named Lapperre CS 3010 Also named Argosy Alize 100 SP		X	X		X		X			
Naida 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 NW O 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 NW O 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 NW O Also named Lapperre Pro I 521		X	X							X
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	

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

June 16th, 2016 C. Schiffer

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

	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 Baseo Q	Phonak Baseo Q15-M Also named Argosy Bossa 15-M	X	X	X	X			X				
	Phonak Baseo Q15-P	X	X	X	X			X				
	Phonak Baseo Q15-SP Also named Argosy Bossa 15-SP	X	X	X	X			X				
	Phonak Baseo Q10-M Also named Argosy Bossa 10-M	X	X	X	X			X				
	Phonak Baseo Q10-SP Also named Argosy Bossa 10-SP	X	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	
	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	

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits
le 16/04/2014 *C. Schmitt*
 LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

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 Nathos S+	Phonak Nathos S+ micro	X	X	X	X			X			
	Phonak Nathos S+ M	X	X	X	X			X			
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 nano also named Argosy Clara nano	X	X								
Phonak Cassia	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			
	Phonak Cassia nano also named Argosy Clara nano	X	X								X
Nathos	Nathos micro	X	X			X		X			
	Nathos M	X	X			X		X			

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits
June 16th 2014 C. Schiflet
 LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

	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	Naida I UP also named Argosy Alize I UP	X	X	X	X			X			
	Naida 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			

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

June 12th, 2014

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

	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 MINI IX	X	X						X			
	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				
Variants		Fit'n' Go [cShell; cShell Soft; xShell, SlimTip Soft]										
	Acoustical connection adapted by earmold, SlimTip, domes by a thin tube inclusive external receiver. Valid for: RIC (receiver in the canal) BTE (behind the ear worn hearing aids)											



LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

June 16th 2014 C. Schaffner

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed