

To whom it may concern

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

DocuSigned by:

Julien SZCZESNIAK

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Declaration of Conformity

Hearing Instrument Systems

We, Sonova AG, Laubisrütistrasse 28, 8712 Stäfa, hereby declare under our sole responsibility that the medical devices Class 2a listed below are in conformity with the applicable provisions of the Medical Device Directive 93/42/EEC inclusive its related Fitting Software Phonak Target 5.1, 5.2, 5.3, 5.4, 6.0, 6.1, 6.2, 7.0, 7.1 (GMDN 60211) and related 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: EN ISO 10993-1; MD Software: EN 62304;
Degrees of Protection (IP code): EN 60529:2013

This declaration is supported by:

Certificate of approval No.: 32433 to the quality standard ISO 13485:2016 issued by GMED and EC Certificate No.: 32438 acc. 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

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Julia SZCZESNIAK

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Product Line and Model	Type	GMDN BTE (34671)	GMDN RIC (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
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Phonak Virto M

Phonak Virto M90-10 NW O (Options: M,P,SP)				X
Phonak Virto M70-10 NW O (Options: M,P,SP)				X
Phonak Virto M50-10 NW O (Options: M,P,SP)				X
Phonak Virto M30-10 NW O (Options: M,P,SP)				X
Phonak Virto M90-312 NW O (Options: M,P,SP)				X
Phonak Virto M70-312 NW O (Options: M,P,SP)				X
Phonak Virto M50-312 NW O (Options: M,P,SP)				X
Phonak Virto M30-312 NW O (Options: M,P,SP)				X
Phonak Virto M90-Titanium (Options: M,P,SP)				X
Phonak Virto M70-Titanium (Options: M,P,SP)				X

DX Inera

DX Inera 9 312 Omni				X
DX Inera 7 312 Omni				X
DX Inera 5 312 Omni				X
DX Inera 3 312 Omni				X
DX Inera 9 10A Omni				X
DX Inera 7 10A Omni				X
DX Inera 5 10A Omni				X
DX Inera 3 10A Omni				X

Vista DX

Vista DX 950 312 Omni				X
Vista DX 750 312 Omni				X
Vista DX 550 312 Omni				X
Vista DX 350 312 Omni				X
Vista DX 950 10A Omni				X
Vista DX 750 10A Omni				X
Vista DX 550 10A Omni				X
Vista DX 350 10A Omni				X

jazz XC Pro

jazz XC Pro 9-312				X
jazz XC Pro 7-312				X
jazz XC Pro 5-312				X

Type	GMDN BTE (34671)	GMDN RIC (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Product Line and Model				

jazz XC Pro 3-312				X
jazz XC Pro 9-10				X
jazz XC Pro 7-10				X
jazz XC Pro 5-10				X
jazz XC Pro 3-10				X

AudioNova DX

AudioNova DX 90 312 Omni				X
AudioNova DX 70 312 Omni				X
AudioNova DX 50 312 Omni				X
AudioNova DX 30 312 Omni				X
AudioNova DX 90 10A Omni				X
AudioNova DX 70 10A Omni				X
AudioNova DX 50 10A Omni				X
AudioNova DX 30 10A Omni				X

RELATE 2.0 Reserve

RELATE 2.0 Reserve 312 Omni				X
RELATE 2.0 Reserve 10A Omni				X

Advance

Advance 870 312 Omni				X
Advance 770 312 Omni				X
Advance 670 312 Omni				X
Advance 470 312 Omni				X
Advance 870 10A Omni				X
Advance 770 10A Omni				X
Advance 670 10A Omni				X
Advance 470 10A Omni				X

Phonak Vitus

Phonak Vitus+ ITE-10 NW O (Options: M,P,SP)				X
Phonak Vitus BTE-micro	X			
Phonak Vitus BTE-P	X			
Phonak Vitus BTE-UP	X			

Type	GMDN BTE (34671)	GMDN RIC (47169)	GMDN ITE (34672)	GMDN ITC/CIC (41209)
Product Line and Model				

Excellence 2

Excellence 2 V8 10A Omni			X	
Excellence 2 V6 10A Omni			X	
Excellence 2 V4 10A Omni			X	
Excellence 2 V2 10A Omni			X	

Lyric4

Lyric4 (Options: XXS, XS, S, M, L, XL, XXL)				X
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Phonak Brio 4

Phonak Brio 4 I-10 NW O (Options: M, P, SP)				X
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Phonak Brio 3

Phonak Brio 3 I-N (Options: M,P,SP)				X
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Phonak Brio 2 I

Phonak Brio 2 I-N (Options: M)				X
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Selectic Luna I

Selectic Luna I9-10 (Options: M, P, SP)				X
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Phonak Virto B Titanium

Phonak Virto B90-Titanium (Options: M, P, SP)				X
Phonak Virto B70-Titanium (Options: M, P, SP)				X

Phonak Virto B

Phonak Virto B90-10 NW O (Options: M,P,SP)				X
Phonak Virto B70-10 NW O (Options: M,P,SP)				X
Phonak Virto B50-10 NW O (Options: M,P,SP)				X
Phonak Virto B30-10 NW O (Options: M,P,SP)				X
Phonak Virto B90-312 NW O (Options: M,P,SP)				X
Phonak Virto B70-312 NW O (Options: M,P,SP)				X
Phonak Virto B50-312 NW O (Options: M,P,SP)				X
Phonak Virto B30-312 NW O (Options: M,P,SP)				X

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