

MDR DoC uPrince2/3

EU Declaration of Conformity⁽¹⁾

Manufacturer: ⁽²⁾	Sonova AG, Laubisrütistrasse 28, 8712 Stäfa, Switzerland																				
Single Registration Number: ⁽³⁾	CH-MF-000015958																				
Authorised Representative: ⁽⁴⁾	Sonova Deutschland GmbH, Max-Eyth-Straße 20, 70736 Fellbach, Germany																				
Single Registration Number: ⁽³⁾	DE-AR-000006322																				
Products covered: ⁽⁵⁾	See Annex 1 ⁽⁶⁾																				
Products intended purpose: ⁽⁷⁾	The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing ⁽⁸⁾																				
Products risk class: ⁽⁹⁾	Class IIa ⁽¹⁰⁾																				
Applicable standards: ⁽¹¹⁾	<table> <tr> <td>IEC 60118-13</td><td>EN 62304</td></tr> <tr> <td>IEC 60118-0</td><td>EN ISO 15223-1</td></tr> <tr> <td>EN 60601-1-2</td><td>ETSI EN 300 328 V2.2.2</td></tr> <tr> <td>EN 60601-1</td><td>EN 301 489-1 V2.2.3 (RIC & BTE)</td></tr> <tr> <td>ISO 20417</td><td>EN 301 489-3 V2.1.2 (BTE)</td></tr> <tr> <td>IEC 62366-1</td><td>EN 301 489-3 V2.3.0 (RIC)</td></tr> <tr> <td>ISO 14971</td><td>ETSI EN 301 489-17 V3.2.4 (BTE)</td></tr> <tr> <td>EN 60601-1-6</td><td>ETSI EN 301 489-17 V3.2.5 (RIC)</td></tr> <tr> <td>EN 62479</td><td>EN 62479 :2010</td></tr> <tr> <td>ISO 10993-1</td><td></td></tr> </table>	IEC 60118-13	EN 62304	IEC 60118-0	EN ISO 15223-1	EN 60601-1-2	ETSI EN 300 328 V2.2.2	EN 60601-1	EN 301 489-1 V2.2.3 (RIC & BTE)	ISO 20417	EN 301 489-3 V2.1.2 (BTE)	IEC 62366-1	EN 301 489-3 V2.3.0 (RIC)	ISO 14971	ETSI EN 301 489-17 V3.2.4 (BTE)	EN 60601-1-6	ETSI EN 301 489-17 V3.2.5 (RIC)	EN 62479	EN 62479 :2010	ISO 10993-1	
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EN 60601-1-6	ETSI EN 301 489-17 V3.2.5 (RIC)																				
EN 62479	EN 62479 :2010																				
ISO 10993-1																					
Applicable common specification: ⁽¹²⁾	None ⁽¹³⁾																				
EC Certificate/Notified Body: ⁽¹⁴⁾	N° 38657, issued by GMED (0459) ⁽¹⁵⁾																				
Conformity Assessment Route: ⁽¹⁶⁾	Annex IX ⁽¹⁷⁾																				
ISO Certificate/Certifying Body: ⁽¹⁸⁾	N° 32433 (ISO 13485:2016), issued by GMED ⁽¹⁹⁾																				
Directive 2014/53/EU: ⁽²⁰⁾	Radio Equipment Directive (RED) ⁽²¹⁾																				
Directive 2011/65/EU: ⁽²²⁾	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) ⁽²³⁾																				
Directive 2015/863/EU: ⁽²⁴⁾	Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (RoHS3) ⁽²⁵⁾																				
Regulation (EC) No. 1907/2006: ⁽²⁶⁾	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) ⁽²⁷⁾																				
Directive 2012/19/EU: ⁽²⁸⁾	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) ⁽²⁹⁾																				

We, Sonova AG under sole responsibility, hereby declare that the products listed in the Annex 1 are in conformity with the legislation detailed above, and Regulation (EU) 2017/745 of the European Parliament and of The Council on medical devices. ⁽³⁰⁾

Stäfa, 05/02/2024
Location, day/month/year ⁽³¹⁾

Stäfa, 05/02/2024
Location, day/month/year ⁽³¹⁾



Blathnaid Feldman
VP Quality Management and Regulatory Affairs ⁽³²⁾



David Sooprayen
Regulatory Affairs Manager ⁽³³⁾

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Annex 1

to EU Declaration of Conformity

Product Reference⁽³⁴⁾	Basic UDI-DI⁽³⁵⁾	UDI-DI	GMDN	Product Name and Firmware version⁽³⁶⁾	Classification Rule (Annex VIII) ⁽³⁷⁾
050-6820-P2	07613389RICWJ	07613389653441	47169	Moxi V1-312 (amber) Firmware: 067-6555	5, 9
050-6820-P7		07613389653786	47169	Moxi V1-312 (pewter) Firmware: 067-6555	5, 9
050-6820-P6		07613389653779	47169	Moxi V1-312 (platinum) Firmware: 067-6555	5, 9
050-6820-R8		07613389653793	47169	Moxi V1-312 (sand) Firmware: 067-6555	5, 9
050-6821-P2	07613389RICWJ	07613389653458	47169	Moxi V3-312 (amber) Firmware: 067-6556	5, 9
050-6821-P8		07613389653830	47169	Moxi V3-312 (charcoal) Firmware: 067-6556	5, 9
050-6821-P4		07613389653809	47169	Moxi V3-312 (espresso) Firmware: 067-6556	5, 9
050-6821-P7		07613389653823	47169	Moxi V3-312 (pewter) Firmware: 067-6556	5, 9
050-6821-P6		07613389653816	47169	Moxi V3-312 (platinum) Firmware: 067-6556	5, 9
050-6821-R8		07613389653847	47169	Moxi V3-312 (sand) Firmware: 067-6556	5, 9
050-6822-P2	07613389RICWJ	07613389653465	47169	Moxi V5-312 (amber) Firmware: 067-6557	5, 9
050-6822-P8		07613389653885	47169	Moxi V5-312 (charcoal) Firmware: 067-6557	5, 9
050-6822-P4		07613389653854	47169	Moxi V5-312 (espresso) Firmware: 067-6557	5, 9
050-6822-P7		07613389653878	47169	Moxi V5-312 (pewter) Firmware: 067-6557	5, 9
050-6822-P6		07613389653861	47169	Moxi V5-312 (platinum) Firmware: 067-6557	5, 9
050-6822-R8		07613389653892	47169	Moxi V5-312 (sand) Firmware: 067-6557	5, 9
050-6823-P2	07613389RICWJ	07613389653472	47169	Moxi V7-312 (amber) Firmware: 067-6558	5, 9
050-6823-P8		07613389653939	47169	Moxi V7-312 (charcoal) Firmware: 067-6558	5, 9
050-6823-P4		07613389653908	47169	Moxi V7-312 (espresso) Firmware: 067-6558	5, 9
050-6823-P7		07613389653922	47169	Moxi V7-312 (pewter) Firmware: 067-6558	5, 9
050-6823-P6		07613389653915	47169	Moxi V7-312 (platinum) Firmware: 067-6558	5, 9
050-6823-R8		07613389653946	47169	Moxi V7-312 (sand) Firmware: 067-6558	5, 9
050-6824-P2	07613389RICWJ	07613389653489	47169	Moxi V9-312 (amber) Firmware: 067-6559	5, 9
050-6824-P8		07613389653984	47169	Moxi V9-312 (charcoal) Firmware: 067-6559	5, 9
050-6824-P4		07613389653953	47169	Moxi V9-312 (espresso) Firmware: 067-6559	5, 9
050-6824-P7		07613389653977	47169	Moxi V9-312 (pewter) Firmware: 067-6559	5, 9
050-6824-P6		07613389653960	47169	Moxi V9-312 (platinum) Firmware: 067-6559	5, 9
050-6824-R8		07613389653991	47169	Moxi V9-312 (sand)	5, 9

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				Firmware: 067-6559	
050-6825-P6	07613389RICWJ	07613389653496	47169	Moxi V-312 FLEX:TRIAL (platinum) Firmware: 067-6559	5, 9
050-6820-P444	07613389RICWJ	07613389656459	47169	Vista V1-312 (espresso) Firmware: 067-6555	5, 9
050-6820-P744		07613389656466	47169	Vista V1-312 (pewter) Firmware: 067-6555	5, 9
050-6820-P644		07613389656428	47169	Vista V1-312 (platinum) Firmware: 067-6555	5, 9
050-6820-R844		07613389656473	47169	Vista V1-312 (sand) Firmware: 067-6555	5, 9
050-6821-P444	07613389RICWJ	07613389656480	47169	Vista V3-312 (espresso) Firmware: 067-6556	5, 9
050-6821-P744		07613389656503	47169	Vista V3-312 (pewter) Firmware: 067-6556	5, 9
050-6821-P644		07613389656497	47169	Vista V3-312 (platinum) Firmware: 067-6556	5, 9
050-6821-R844		07613389656510	47169	Vista V3-312 (sand) Firmware: 067-6556	5, 9
050-6822-P444	07613389RICWJ	07613389656527	47169	Vista V5-312 (espresso) Firmware: 067-6557	5, 9
050-6822-P744		07613389656541	47169	Vista V5-312 (pewter) Firmware: 067-6557	5, 9
050-6822-P644		07613389656534	47169	Vista V5-312 (platinum) Firmware: 067-6557	5, 9
050-6822-R844		07613389656558	47169	Vista V5-312 (sand) Firmware: 067-6557	5, 9
050-6823-P444	07613389RICWJ	07613389656565	47169	Vista V7-312 (espresso) Firmware: 067-6558	5, 9
050-6823-P744		07613389656589	47169	Vista V7-312 (pewter) Firmware: 067-6558	5, 9
050-6823-P644		07613389656572	47169	Vista V7-312 (platinum) Firmware: 067-6558	5, 9
050-6823-R844		07613389656596	47169	Vista V7-312 (sand) Firmware: 067-6558	5, 9
050-6824-P444	07613389RICWJ	07613389656602	47169	Vista V9-312 (espresso) Firmware: 067-6559	5, 9
050-6824-P744		07613389656626	47169	Vista V9-312 (pewter) Firmware: 067-6559	5, 9
050-6824-P644		07613389656619	47169	Vista V9-312 (platinum) Firmware: 067-6559	5, 9
050-6824-R844		07613389656633	47169	Vista V9-312 (sand) Firmware: 067-6559	5, 9
050-6856-P444	07613389RICWJ	07613389656930	47169	Vista V-312 Select (espresso) Firmware: 067-6559	5, 9
050-6856-P744		07613389656978	47169	Vista V-312 Select (pewter) Firmware: 067-6559	5, 9
050-6856-P644		07613389656961	47169	Vista V-312 Select (platinum) Firmware: 067-6559	5, 9
050-6856-R844		07613389656985	47169	Vista V-312 Select (sand) Firmware: 067-6559	5, 9
050-6825-P644	07613389RICWJ	07613389656640	47169	Vista V-312 trial (platinum) Firmware: 067-6559	5, 9
050-6838-U6	07613389RICWJ	07613389654769	47169	sound FS 1-R312 (carbon black) Firmware: 067-6555	5, 9
050-6838-UA		07613389654776	47169	sound FS 1-R312 (cashmere beige) Firmware: 067-6555	5, 9
050-6838-UC		07613389654790	47169	sound FS 1-R312 (metallic anthracite) Firmware: 067-6555	5, 9
050-6838-UB		07613389654783	47169	sound FS 1-R312 (mocha brown)	5, 9

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				Firmware: 067-6555	
050-6838-U4		07613389653175	47169	sound FS 1-R312 (sterling silver) Firmware: 067-6555	5, 9
050-6839-U6		07613389654806	47169	sound FS 3-R312 (carbon black) Firmware: 067-6556	5, 9
050-6839-UA		07613389654813	47169	sound FS 3-R312 (cashmere beige) Firmware: 067-6556	5, 9
050-6839-UC	07613389RICWJ	07613389654837	47169	sound FS 3-R312 (metallic anthracite) Firmware: 067-6556	5, 9
050-6839-UB		07613389654820	47169	sound FS 3-R312 (mocha brown) Firmware: 067-6556	5, 9
050-6839-U4		07613389653182	47169	sound FS 3-R312 (sterling silver) Firmware: 067-6556	5, 9
050-6840-U6		07613389653090	47169	sound FS 5-R312 (carbon black) Firmware: 067-6557	5, 9
050-6840-UA		07613389653106	47169	sound FS 5-R312 (cashmere beige) Firmware: 067-6557	5, 9
050-6840-UC	07613389RICWJ	07613389655025	47169	sound FS 5-R312 (metallic anthracite) Firmware: 067-6557	5, 9
050-6840-UB		07613389655018	47169	sound FS 5-R312 (mocha brown) Firmware: 067-6557	5, 9
050-6840-U4		07613389653199	47169	sound FS 5-R312 (sterling silver) Firmware: 067-6557	5, 9
050-6841-U6		07613389655032	47169	sound FS 7-R312 (carbon black) Firmware: 067-6558	5, 9
050-6841-UA		07613389655049	47169	sound FS 7-R312 (cashmere beige) Firmware: 067-6558	5, 9
050-6841-UC	07613389RICWJ	07613389655063	47169	sound FS 7-R312 (metallic anthracite) Firmware: 067-6558	5, 9
050-6841-UB		07613389655056	47169	sound FS 7-R312 (mocha brown) Firmware: 067-6558	5, 9
050-6841-U4		07613389653205	47169	sound FS 7-R312 (sterling silver) Firmware: 067-6558	5, 9
050-6842-U6		07613389655070	47169	sound FS 9-R312 (carbon black) Firmware: 067-6559	5, 9
050-6842-UA		07613389655087	47169	sound FS 9-R312 (cashmere beige) Firmware: 067-6559	5, 9
050-6842-UC	07613389RICWJ	07613389655100	47169	sound FS 9-R312 (metallic anthracite) Firmware: 067-6559	5, 9
050-6842-UB		07613389655094	47169	sound FS 9-R312 (mocha brown) Firmware: 067-6559	5, 9
050-6842-U4		07613389654615	47169	sound FS 9-R312 (sterling silver) Firmware: 067-6559	5, 9
050-6843-U4	07613389RICWJ	07613389654622	47169	sound FS R312 myChoice (sterling silver) Firmware: 067-6559	5, 9
050-6820-P450		07613389678383	47169	Advance 272 312 (espresso) Firmware: 067-6555	5, 9
050-6820-P750		07613389678406	47169	Advance 272 312 (pewter) Firmware: 067-6555	5, 9
050-6820-P650	07613389RICWJ	07613389678390	47169	Advance 272 312 (platinum) Firmware: 067-6555	5, 9
050-6820-R850		07613389679717	47169	Advance 272 312 (sand) Firmware: 067-6555	5, 9
050-6821-P450		07613389679724	47169	Advance 372 312 (espresso) Firmware: 067-6556	5, 9
050-6821-P750		07613389679748	47169	Advance 372 312 (pewter) Firmware: 067-6556	5, 9
050-6821-P650	07613389RICWJ	07613389679731	47169	Advance 372 312 (platinum) Firmware: 067-6556	5, 9

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050-6821-R850		07613389679755	47169	Advance 372 312 (sand) Firmware: 067-6556	5, 9
050-6822-P450	07613389RICWJ	07613389679762	47169	Advance 472 312 (espresso) Firmware: 067-6557	5, 9
050-6822-P750		07613389679786	47169	Advance 472 312 (pewter) Firmware: 067-6557	5, 9
050-6822-P650		07613389679779	47169	Advance 472 312 (platinum) Firmware: 067-6557	5, 9
050-6822-R850		07613389679793	47169	Advance 472 312 (sand) Firmware: 067-6557	5, 9
050-6823-P450	07613389RICWJ	07613389679809	47169	Advance 572 312 (espresso) Firmware: 067-6558	5, 9
050-6823-P750		07613389679823	47169	Advance 572 312 (pewter) Firmware: 067-6558	5, 9
050-6823-P650		07613389679816	47169	Advance 572 312 (platinum) Firmware: 067-6558	5, 9
050-6823-R850		07613389679830	47169	Advance 572 312 (sand) Firmware: 067-6558	5, 9
050-6824-P450	07613389RICWJ	07613389679847	47169	Advance 672 312 (espresso) Firmware: 067-6559	5, 9
050-6824-P750		07613389679861	47169	Advance 672 312 (pewter) Firmware: 067-6559	5, 9
050-6824-P650		07613389679854	47169	Advance 672 312 (platinum) Firmware: 067-6559	5, 9
050-6824-R850		07613389679878	47169	Advance 672 312 (sand) Firmware: 067-6559	5, 9
050-6825-P650	07613389RICWJ	07613389679885	47169	Advance 72 312 trial (platinum) Firmware: 067-6559	5, 9
050-6823-P476	07613389RICWJ	07613389680621	47169	Relate 4.0 Gold RIC 312 (espresso) Firmware: 067-6558	5, 9
050-6823-P676		07613389680669	47169	Relate 4.0 Gold RIC 312 (platinum) Firmware: 067-6558	5, 9
050-6823-R876		07613389680737	47169	Relate 4.0 Gold RIC 312 (sand) Firmware: 067-6558	5, 9
050-6824-P476	07613389RICWJ	07613389680751	47169	Relate 4.0 Platinum RIC 312 (espresso) Firmware: 067-6559	5, 9
050-6824-P676		07613389680799	47169	Relate 4.0 Platinum RIC 312 (platinum) Firmware: 067-6559	5, 9
050-6824-R876		07613389680867	47169	Relate 4.0 Platinum RIC 312 (sand) Firmware: 067-6559	5, 9
050-6826-P2	07613389BTEV7	07613389653502	34671	Stride V1-PR (amber) Firmware: 067-6560	5, 9
050-6826-P7		07613389654011	34671	Stride V1-PR (pewter) Firmware: 067-6560	5, 9
050-6826-P6		07613389654004	34671	Stride V1-PR (platinum) Firmware: 067-6560	5, 9
050-6826-R8		07613389654028	34671	Stride V1-PR (sand) Firmware: 067-6560	5, 9
050-6827-P2	07613389BTEV7	07613389653519	34671	Stride V3-PR (amber) Firmware: 067-6561	5, 9
050-6827-P8		07613389654066	34671	Stride V3-PR (charcoal) Firmware: 067-6561	5, 9
050-6827-P4		07613389654035	34671	Stride V3-PR (espresso) Firmware: 067-6561	5, 9
050-6827-P7		07613389654059	34671	Stride V3-PR (pewter) Firmware: 067-6561	5, 9
050-6827-P6		07613389654042	34671	Stride V3-PR (platinum) Firmware: 067-6561	5, 9
050-6827-R8		07613389654073	34671	Stride V3-PR (sand) Firmware: 067-6561	5, 9

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050-6828-P2	07613389BTEV7	07613389653526	34671	Stride V5-PR (amber) Firmware: 067-6562	5, 9
050-6828-P8		07613389654110	34671	Stride V5-PR (charcoal) Firmware: 067-6562	5, 9
050-6828-P4		07613389654080	34671	Stride V5-PR (espresso) Firmware: 067-6562	5, 9
050-6828-P7		07613389654103	34671	Stride V5-PR (pewter) Firmware: 067-6562	5, 9
050-6828-P6		07613389654097	34671	Stride V5-PR (platinum) Firmware: 067-6562	5, 9
050-6828-R8		07613389654127	34671	Stride V5-PR (sand) Firmware: 067-6562	5, 9
050-6829-P2	07613389BTEV7	07613389653533	34671	Stride V7-PR (amber) Firmware: 067-6563	5, 9
050-6829-P8		07613389654165	34671	Stride V7-PR (charcoal) Firmware: 067-6563	5, 9
050-6829-P4		07613389654134	34671	Stride V7-PR (espresso) Firmware: 067-6563	5, 9
050-6829-P7		07613389654158	34671	Stride V7-PR (pewter) Firmware: 067-6563	5, 9
050-6829-P6		07613389654141	34671	Stride V7-PR (platinum) Firmware: 067-6563	5, 9
050-6829-R8		07613389654172	34671	Stride V7-PR (sand) Firmware: 067-6563	5, 9
050-6830-P2	07613389BTEV7	07613389653540	34671	Stride V9-PR (amber) Firmware: 067-6564	5, 9
050-6830-P8		07613389654219	34671	Stride V9-PR (charcoal) Firmware: 067-6564	5, 9
050-6830-P4		07613389654189	34671	Stride V9-PR (espresso) Firmware: 067-6564	5, 9
050-6830-P7		07613389654202	34671	Stride V9-PR (pewter) Firmware: 067-6564	5, 9
050-6830-P6		07613389654196	34671	Stride V9-PR (platinum) Firmware: 067-6564	5, 9
050-6830-R8		07613389654226	34671	Stride V9-PR (sand) Firmware: 067-6564	5, 9
050-6831-P6	07613389BTEV7	07613389653557	34671	Stride V-PR FLEX:TRIAL (platinum) Firmware: 067-6564	5, 9
050-6826-P444	07613389BTEV7	07613389656657	34671	Vista V1-PR (espresso) Firmware: 067-6560	5, 9
050-6826-P744		07613389656664	34671	Vista V1-PR (pewter) Firmware: 067-6560	5, 9
050-6826-P644		07613389656435	34671	Vista V1-PR (platinum) Firmware: 067-6560	5, 9
050-6826-R844		07613389656671	34671	Vista V1-PR (sand) Firmware: 067-6560	5, 9
050-6827-P444	07613389BTEV7	07613389656688	34671	Vista V3-PR (espresso) Firmware: 067-6561	5, 9
050-6827-P744		07613389656701	34671	Vista V3-PR (pewter) Firmware: 067-6561	5, 9
050-6827-P644		07613389656695	34671	Vista V3-PR (platinum) Firmware: 067-6561	5, 9
050-6827-R844		07613389656718	34671	Vista V3-PR (sand) Firmware: 067-6561	5, 9
050-6828-P444	07613389BTEV7	07613389657258	34671	Vista V5-PR (espresso) Firmware: 067-6562	5, 9
050-6828-P744		07613389657272	34671	Vista V5-PR (pewter) Firmware: 067-6562	5, 9
050-6828-P644		07613389657265	34671	Vista V5-PR (platinum) Firmware: 067-6562	5, 9

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050-6828-R844		07613389657289	34671	Vista V5-PR (sand) Firmware: 067-6562	5, 9
050-6829-P444	07613389BTEV7	07613389657296	34671	Vista V7-PR (espresso) Firmware: 067-6563	5, 9
050-6829-P744		07613389657319	34671	Vista V7-PR (pewter) Firmware: 067-6563	5, 9
050-6829-P644		07613389657302	34671	Vista V7-PR (platinum) Firmware: 067-6563	5, 9
050-6829-R844		07613389657371	34671	Vista V7-PR (sand) Firmware: 067-6563	5, 9
050-6830-P444	07613389BTEV7	07613389657326	34671	Vista V9-PR (espresso) Firmware: 067-6564	5, 9
050-6830-P744		07613389657340	34671	Vista V9-PR (pewter) Firmware: 067-6564	5, 9
050-6830-P644		07613389657333	34671	Vista V9-PR (platinum) Firmware: 067-6564	5, 9
050-6830-R844		07613389657357	34671	Vista V9-PR (sand) Firmware: 067-6564	5, 9
050-6857-P444	07613389BTEV7	07613389656947	34671	Vista V-PR Select (espresso) Firmware: 067-6564	5, 9
050-6857-P744		07613389657005	34671	Vista V-PR Select (pewter) Firmware: 067-6564	5, 9
050-6857-P644		07613389656992	34671	Vista V-PR Select (platinum) Firmware: 067-6564	5, 9
050-6857-R844		07613389658910	34671	Vista V-PR Select (sand) Firmware: 067-6564	5, 9
050-6831-P644	07613389BTEV7	07613389657364	34671	Vista V-PR trial (platinum) Firmware: 067-6564	5, 9
050-6844-U6	07613389BTEV7	07613389654486	34671	AQ beat FS 1-R (carbon black) Firmware: 067-6560	5, 9
050-6844-UA		07613389654493	34671	AQ beat FS 1-R (cashmere beige) Firmware: 067-6560	5, 9
050-6844-UC		07613389655117	34671	AQ beat FS 1-R (metallic anthracite) Firmware: 067-6560	5, 9
050-6844-UB		07613389654509	34671	AQ beat FS 1-R (mocha brown) Firmware: 067-6560	5, 9
050-6844-U4		07613389654639	34671	AQ beat FS 1-R (sterling silver) Firmware: 067-6560	5, 9
050-6845-U6	07613389BTEV7	07613389655124	34671	AQ beat FS 3-R (carbon black) Firmware: 067-6561	5, 9
050-6845-UA		07613389655131	34671	AQ beat FS 3-R (cashmere beige) Firmware: 067-6561	5, 9
050-6845-UC		07613389655155	34671	AQ beat FS 3-R (metallic anthracite) Firmware: 067-6561	5, 9
050-6845-UB		07613389655148	34671	AQ beat FS 3-R (mocha brown) Firmware: 067-6561	5, 9
050-6845-U4		07613389654646	34671	AQ beat FS 3-R (sterling silver) Firmware: 067-6561	5, 9
050-6846-U6	07613389BTEV7	07613389655162	34671	AQ beat FS 5-R (carbon black) Firmware: 067-6562	5, 9
050-6846-UA		07613389655179	34671	AQ beat FS 5-R (cashmere beige) Firmware: 067-6562	5, 9
050-6846-UC		07613389655193	34671	AQ beat FS 5-R (metallic anthracite) Firmware: 067-6562	5, 9
050-6846-UB		07613389655186	34671	AQ beat FS 5-R (mocha brown) Firmware: 067-6562	5, 9
050-6846-U4		07613389654653	34671	AQ beat FS 5-R (sterling silver) Firmware: 067-6562	5, 9
050-6847-U6	07613389BTEV7	07613389655209	34671	AQ beat FS 7-R (carbon black) Firmware: 067-6563	5, 9

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050-6847-UA		07613389655216	34671	AQ beat FS 7-R (cashmere beige) Firmware: 067-6563	5, 9
050-6847-UC		07613389655230	34671	AQ beat FS 7-R (metallic anthracite) Firmware: 067-6563	5, 9
050-6847-UB		07613389655223	34671	AQ beat FS 7-R (mocha brown) Firmware: 067-6563	5, 9
050-6847-U4		07613389654660	34671	AQ beat FS 7-R (sterling silver) Firmware: 067-6563	5, 9
050-6848-U6	07613389BTEV7	07613389655247	34671	AQ beat FS 9-R (carbon black) Firmware: 067-6564	5, 9
050-6848-UA		07613389655254	34671	AQ beat FS 9-R (cashmere beige) Firmware: 067-6564	5, 9
050-6848-UC		07613389655278	34671	AQ beat FS 9-R (metallic anthracite) Firmware: 067-6564	5, 9
050-6848-UB		07613389655261	34671	AQ beat FS 9-R (mocha brown) Firmware: 067-6564	5, 9
050-6848-U4		07613389654677	34671	AQ beat FS 9-R (sterling silver) Firmware: 067-6564	5, 9
050-6849-U4	07613389BTEV7	07613389654684	34671	AQ beat FS R myChoice (sterling silver) Firmware: 067-6564	5, 9
050-6826-P450	07613389BTEV7	07613389679892	34671	Advance 272 PR (espresso) Firmware: 067-6560	5, 9
050-6826-P750		07613389679915	34671	Advance 272 PR (pewter) Firmware: 067-6560	5, 9
050-6826-P650		07613389679908	34671	Advance 272 PR (platinum) Firmware: 067-6560	5, 9
050-6826-R850		07613389679922	34671	Advance 272 PR (sand) Firmware: 067-6560	5, 9
050-6827-P450		07613389679939	34671	Advance 372 PR (espresso) Firmware: 067-6561	5, 9
050-6827-P750	07613389BTEV7	07613389679953	34671	Advance 372 PR (pewter) Firmware: 067-6561	5, 9
050-6827-P650		07613389679946	34671	Advance 372 PR (platinum) Firmware: 067-6561	5, 9
050-6827-R850		07613389679960	34671	Advance 372 PR (sand) Firmware: 067-6561	5, 9
050-6828-P450		07613389679977	34671	Advance 472 PR (espresso) Firmware: 067-6562	5, 9
050-6828-P750	07613389BTEV7	07613389679991	34671	Advance 472 PR (pewter) Firmware: 067-6562	5, 9
050-6828-P650		07613389679984	34671	Advance 472 PR (platinum) Firmware: 067-6562	5, 9
050-6828-R850		07613389680003	34671	Advance 472 PR (sand) Firmware: 067-6562	5, 9
050-6829-P450		07613389680010	34671	Advance 572 PR (espresso) Firmware: 067-6563	5, 9
050-6829-P750	07613389BTEV7	07613389680034	34671	Advance 572 PR (pewter) Firmware: 067-6563	5, 9
050-6829-P650		07613389680027	34671	Advance 572 PR (platinum) Firmware: 067-6563	5, 9
050-6829-R850		07613389680041	34671	Advance 572 PR (sand) Firmware: 067-6563	5, 9
050-6830-P450		07613389680058	34671	Advance 672 PR (espresso) Firmware: 067-6564	5, 9
050-6830-P750	07613389BTEV7	07613389680072	34671	Advance 672 PR (pewter) Firmware: 067-6564	5, 9
050-6830-P650		07613389680065	34671	Advance 672 PR (platinum) Firmware: 067-6564	5, 9
050-6830-R850		07613389680089	34671	Advance 672 PR (sand) Firmware: 067-6564	5, 9

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050-6831-P650	07613389BTEV7	07613389680096	34671	Advance72 PR trial (platinum) Firmware: 067-6564	5, 9
050-6829-P476	07613389BTEV7	07613389681215	34671	Relate4.0 Gold BTE R (espresso) Firmware: 067-6563	5, 9
050-6829-P676		07613389681253	34671	Relate4.0 Gold BTE R (platinum) Firmware: 067-6563	5, 9
050-6829-R876		07613389681321	34671	Relate4.0 Gold BTE R (sand) Firmware: 067-6563	5, 9
050-6830-P476	07613389BTEV7	07613389681345	34671	Relate4.0 Platinum BTE R (espresso) Firmware: 067-6564	5, 9
050-6830-P676		07613389681383	34671	Relate4.0 Platinum BTE R (platinum) Firmware: 067-6564	5, 9
050-6830-R876		07613389681451	34671	Relate4.0 Platinum BTE R (sand) Firmware: 067-6564	5, 9
050-6827-P476	07613389BTEV7	07613389680980	34671	Relate4.0 Silver BTE R (espresso) Firmware: 067-6561	5, 9
050-6827-P676		07613389681024	34671	Relate4.0 Silver BTE R (platinum) Firmware: 067-6561	5, 9
050-6827-R876		07613389681093	34671	Relate4.0 Silver BTE R (sand) Firmware: 067-6561	5, 9
050-6820-P465	07613389RICWJ	07613389657609	47169	AudioNova V1-312 (espresso) Firmware: 067-6555	5, 9
050-6820-P765		07613389657616	47169	AudioNova V1-312 (pewter) Firmware: 067-6555	5, 9
050-6820-P665		07613389657586	47169	AudioNova V1-312 (platinum) Firmware: 067-6555	5, 9
050-6820-R865		07613389657623	47169	AudioNova V1-312 (sand) Firmware: 067-6555	5, 9
050-6821-P465	07613389RICWJ	07613389657630	47169	AudioNova V3-312 (espresso) Firmware: 067-6556	5, 9
050-6821-P765		07613389657654	47169	AudioNova V3-312 (pewter) Firmware: 067-6556	5, 9
050-6821-P665		07613389657647	47169	AudioNova V3-312 (platinum) Firmware: 067-6556	5, 9
050-6821-R865		07613389657661	47169	AudioNova V3-312 (sand) Firmware: 067-6556	5, 9
050-6822-P465	07613389RICWJ	07613389657678	47169	AudioNova V5-312 (espresso) Firmware: 067-6557	5, 9
050-6822-P765		07613389657692	47169	AudioNova V5-312 (pewter) Firmware: 067-6557	5, 9
050-6822-P665		07613389657685	47169	AudioNova V5-312 (platinum) Firmware: 067-6557	5, 9
050-6822-R865		07613389657708	47169	AudioNova V5-312 (sand) Firmware: 067-6557	5, 9
050-6823-P465	07613389RICWJ	07613389657715	47169	AudioNova V7-312 (espresso) Firmware: 067-6558	5, 9
050-6823-P765		07613389657739	47169	AudioNova V7-312 (pewter) Firmware: 067-6558	5, 9
050-6823-P665		07613389657722	47169	AudioNova V7-312 (platinum) Firmware: 067-6558	5, 9
050-6823-R865		07613389657746	47169	AudioNova V7-312 (sand) Firmware: 067-6558	5, 9
050-6824-P465	07613389RICWJ	07613389657753	47169	AudioNova V9-312 (espresso) Firmware: 067-6559	5, 9
050-6824-P765		07613389657791	47169	AudioNova V9-312 (pewter) Firmware: 067-6559	5, 9
050-6824-P665		07613389657760	47169	AudioNova V9-312 (platinum) Firmware: 067-6559	5, 9
050-6824-R865		07613389657777	47169	AudioNova V9-312 (sand) Firmware: 067-6559	5, 9

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050-6825-P665	07613389RICWJ	07613389657784	47169	AudioNova V-312 trial (platinum) Firmware: 067-6559	5, 9
050-6821-P758	07613389RICWJ	07613389680454	47169	SoniTon UP7 12 312 (pewter) Firmware: 067-6556	5, 9
050-6821-P658		07613389680416	47169	SoniTon UP7 12 312 (platinum) Firmware: 067-6556	5, 9
050-6821-R858		07613389680485	47169	SoniTon UP7 12 312 (sand) Firmware: 067-6556	5, 9
050-6822-P758	07613389RICWJ	07613389680560	47169	SoniTon UP7 16 312 (pewter) Firmware: 067-6557	5, 9
050-6822-P658		07613389680539	47169	SoniTon UP7 16 312 (platinum) Firmware: 067-6557	5, 9
050-6822-R858		07613389680591	47169	SoniTon UP7 16 312 (sand) Firmware: 067-6557	5, 9
050-6823-P758	07613389RICWJ	07613389680683	47169	SoniTon UP7 20 312 (pewter) Firmware: 067-6558	5, 9
050-6823-P658		07613389680645	47169	SoniTon UP7 20 312 (platinum) Firmware: 067-6558	5, 9
050-6823-R858		07613389680713	47169	SoniTon UP7 20 312 (sand) Firmware: 067-6558	5, 9
050-6820-P758	07613389RICWJ	07613389680348	47169	SoniTon UP7 8 312 (pewter) Firmware: 067-6555	5, 9
050-6820-P658		07613389680324	47169	SoniTon UP7 8 312 (platinum) Firmware: 067-6555	5, 9
050-6820-R858		07613389680362	47169	SoniTon UP7 8 312 (sand) Firmware: 067-6555	5, 9
050-6824-P758	07613389RICWJ	07613389680812	47169	SoniTon UP7 Premium 312 (pewter) Firmware: 067-6559	5, 9
050-6824-P658		07613389680775	47169	SoniTon UP7 Premium 312 (platinum) Firmware: 067-6559	5, 9
050-6824-R858		07613389680843	47169	SoniTon UP7 Premium 312 (sand) Firmware: 067-6559	5, 9
050-6825-P658	07613389RICWJ	07613389680881	47169	SoniTon UP7 312 trial (platinum) Firmware: 067-6559	5, 9
050-6820-P472	07613389RICWJ	07613389680317	47169	scala V1-312 (espresso) Firmware: 067-6555	5, 9
050-6820-P772		07613389680355	47169	scala V1-312 (pewter) Firmware: 067-6555	5, 9
050-6820-P672		07613389680331	47169	scala V1-312 (platinum) Firmware: 067-6555	5, 9
050-6820-R872		07613389680379	47169	scala V1-312 (sand) Firmware: 067-6555	5, 9
050-6821-P472	07613389RICWJ	07613389680386	47169	scala V3-312 (espresso) Firmware: 067-6556	5, 9
050-6821-P772		07613389680461	47169	scala V3-312 (pewter) Firmware: 067-6556	5, 9
050-6821-P672		07613389680423	47169	scala V3-312 (platinum) Firmware: 067-6556	5, 9
050-6821-R872		07613389680492	47169	scala V3-312 (sand) Firmware: 067-6556	5, 9
050-6822-P472	07613389RICWJ	07613389680515	47169	scala V5-312 (espresso) Firmware: 067-6557	5, 9
050-6822-P772		07613389680577	47169	scala V5-312 (pewter) Firmware: 067-6557	5, 9
050-6822-P672		07613389680546	47169	scala V5-312 (platinum) Firmware: 067-6557	5, 9
050-6822-R872		07613389680607	47169	scala V5-312 (sand) Firmware: 067-6557	5, 9
050-6823-P472	07613389RICWJ	07613389680614	47169	scala V7-312 (espresso) Firmware: 067-6558	5, 9

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050-6823-P672		07613389680652	47169	scala V7-312 (platinum) Firmware: 067-6558	5, 9
050-6823-R872		07613389680720	47169	scala V7-312 (sand) Firmware: 067-6558	5, 9
050-6824-P472	07613389RICWJ	07613389680744	47169	scala V9-312 (espresso) Firmware: 067-6559	5, 9
050-6824-P772		07613389680829	47169	scala V9-312 (pewter) Firmware: 067-6559	5, 9
050-6824-P672		07613389680782	47169	scala V9-312 (platinum) Firmware: 067-6559	5, 9
050-6824-R872		07613389680850	47169	scala V9-312 (sand) Firmware: 067-6559	5, 9
050-6825-P672	07613389RICWJ	07613389680898	47169	scala V-312 trial (platinum) Firmware: 067-6559	5, 9
050-6821-P748	07613389RICWJ	07613389680447	47169	ViO H126 (pewter) Firmware: 067-6556	5, 9
050-6821-P648		07613389680409	47169	ViO H126 (platinum) Firmware: 067-6556	5, 9
050-6821-R848		07613389680478	47169	ViO H126 (sand) Firmware: 067-6556	5, 9
050-6822-P748	07613389RICWJ	07613389680553	47169	ViO H226 (pewter) Firmware: 067-6557	5, 9
050-6822-P648		07613389680522	47169	ViO H226 (platinum) Firmware: 067-6557	5, 9
050-6822-R848		07613389680584	47169	ViO H226 (sand) Firmware: 067-6557	5, 9
050-6823-P748	07613389RICWJ	07613389680676	47169	ViO H326 (pewter) Firmware: 067-6558	5, 9
050-6823-P648		07613389680638	47169	ViO H326 (platinum) Firmware: 067-6558	5, 9
050-6823-R848		07613389680706	47169	ViO H326 (sand) Firmware: 067-6558	5, 9
050-6824-P748	07613389RICWJ	07613389680805	47169	ViO H426 (pewter) Firmware: 067-6559	5, 9
050-6824-P648		07613389680768	47169	ViO H426 (platinum) Firmware: 067-6559	5, 9
050-6824-R848		07613389680836	47169	ViO H426 (sand) Firmware: 067-6559	5, 9
050-6825-P648	07613389RICWJ	07613389680874	47169	ViO HD26 Demo (platinum) Firmware: 067-6559	5, 9
050-6826-P465	07613389BTEV7	07613389657807	34671	AudioNova V1-PR (espresso) Firmware: 067-6560	5, 9
050-6826-P765		07613389657814	34671	AudioNova V1-PR (pewter) Firmware: 067-6560	5, 9
050-6826-P665		07613389657593	34671	AudioNova V1-PR (platinum) Firmware: 067-6560	5, 9
050-6826-R865		07613389657821	34671	AudioNova V1-PR (sand) Firmware: 067-6560	5, 9
050-6827-P465	07613389BTEV7	07613389657838	34671	AudioNova V3-PR (espresso) Firmware: 067-6561	5, 9
050-6827-P765		07613389657852	34671	AudioNova V3-PR (pewter) Firmware: 067-6561	5, 9
050-6827-P665		07613389657845	34671	AudioNova V3-PR (platinum) Firmware: 067-6561	5, 9
050-6827-R865		07613389657869	34671	AudioNova V3-PR (sand) Firmware: 067-6561	5, 9
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050-6828-P665		07613389657883	34671	AudioNova V5-PR (platinum) Firmware: 067-6562	5, 9
050-6828-R865		07613389657906	34671	AudioNova V5-PR (sand) Firmware: 067-6562	5, 9
050-6829-P465	07613389BTEV7	07613389657913	34671	AudioNova V7-PR (espresso) Firmware: 067-6563	5, 9
050-6829-P765		07613389657937	34671	AudioNova V7-PR (pewter) Firmware: 067-6563	5, 9
050-6829-P665		07613389657920	34671	AudioNova V7-PR (platinum) Firmware: 067-6563	5, 9
050-6829-R865		07613389657944	34671	AudioNova V7-PR (sand) Firmware: 067-6563	5, 9
050-6830-P465	07613389BTEV7	07613389657951	34671	AudioNova V9-PR (espresso) Firmware: 067-6564	5, 9
050-6830-P765		07613389657975	34671	AudioNova V9-PR (pewter) Firmware: 067-6564	5, 9
050-6830-P665		07613389657968	34671	AudioNova V9-PR (platinum) Firmware: 067-6564	5, 9
050-6830-R865		07613389658002	34671	AudioNova V9-PR (sand) Firmware: 067-6564	5, 9
050-6831-P665	07613389BTEV7	07613389658019	34671	AudioNova V-PR trial (platinum) Firmware: 067-6564	5, 9
050-6827-P758	07613389BTEV7	07613389681048	34671	SoniTon UP7 12 PR (pewter) Firmware: 067-6561	5, 9
050-6827-P658		07613389681000	34671	SoniTon UP7 12 PR (platinum) Firmware: 067-6561	5, 9
050-6827-R858		07613389681079	34671	SoniTon UP7 12 PR (sand) Firmware: 067-6561	5, 9
050-6828-P758	07613389BTEV7	07613389681154	34671	SoniTon UP7 16 PR (pewter) Firmware: 067-6562	5, 9
050-6828-P658		07613389681123	34671	SoniTon UP7 16 PR (platinum) Firmware: 067-6562	5, 9
050-6828-R858		07613389681185	34671	SoniTon UP7 16 PR (sand) Firmware: 067-6562	5, 9
050-6829-P758	07613389BTEV7	07613389681277	34671	SoniTon UP7 20 PR (pewter) Firmware: 067-6563	5, 9
050-6829-P658		07613389681239	34671	SoniTon UP7 20 PR (platinum) Firmware: 067-6563	5, 9
050-6829-R858		07613389681307	34671	SoniTon UP7 20 PR (sand) Firmware: 067-6563	5, 9
050-6826-P758	07613389BTEV7	07613389680935	34671	SoniTon UP7 8 PR (pewter) Firmware: 067-6560	5, 9
050-6826-P658		07613389680911	34671	SoniTon UP7 8 PR (platinum) Firmware: 067-6560	5, 9
050-6826-R858		07613389680959	34671	SoniTon UP7 8 PR (sand) Firmware: 067-6560	5, 9
050-6830-P758	07613389BTEV7	07613389681406	34671	SoniTon UP7 Premium PR (pewter) Firmware: 067-6564	5, 9
050-6830-P658		07613389681369	34671	SoniTon UP7 Premium PR (platinum) Firmware: 067-6564	5, 9
050-6830-R858		07613389681437	34671	SoniTon UP7 Premium PR (sand) Firmware: 067-6564	5, 9
050-6831-P658	07613389BTEV7	07613389681475	34671	SoniTon UP7 PR trial (platinum) Firmware: 067-6564	5, 9
050-6826-P472	07613389BTEV7	07613389680904	34671	scala V1-PR (espresso) Firmware: 067-6560	5, 9
050-6826-P772		07613389680942	34671	scala V1-PR (pewter) Firmware: 067-6560	5, 9

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050-6826-P672		07613389680928	34671	scala V1-PR (platinum) Firmware: 067-6560	5, 9
050-6826-R872		07613389680966	34671	scala V1-PR (sand) Firmware: 067-6560	5, 9
050-6827-P472	07613389BTEV7	07613389680973	34671	scala V3-PR (espresso) Firmware: 067-6561	5, 9
050-6827-P772		07613389681055	34671	scala V3-PR (pewter) Firmware: 067-6561	5, 9
050-6827-P672		07613389681017	34671	scala V3-PR (platinum) Firmware: 067-6561	5, 9
050-6827-R872		07613389681086	34671	scala V3-PR (sand) Firmware: 067-6561	5, 9
050-6828-P472	07613389BTEV7	07613389681109	34671	scala V5-PR (espresso) Firmware: 067-6562	5, 9
050-6828-P772		07613389681161	34671	scala V5-PR (pewter) Firmware: 067-6562	5, 9
050-6828-P672		07613389681130	34671	scala V5-PR (platinum) Firmware: 067-6562	5, 9
050-6828-R872		07613389681192	34671	scala V5-PR (sand) Firmware: 067-6562	5, 9
050-6829-P472	07613389BTEV7	07613389681208	34671	scala V7-PR (espresso) Firmware: 067-6563	5, 9
050-6829-P772		07613389681284	34671	scala V7-PR (pewter) Firmware: 067-6563	5, 9
050-6829-P672		07613389681246	34671	scala V7-PR (platinum) Firmware: 067-6563	5, 9
050-6829-R872		07613389681314	34671	scala V7-PR (sand) Firmware: 067-6563	5, 9
050-6830-P472	07613389BTEV7	07613389681338	34671	scala V9-PR (espresso) Firmware: 067-6564	5, 9
050-6830-P772		07613389681413	34671	scala V9-PR (pewter) Firmware: 067-6564	5, 9
050-6830-P672		07613389681376	34671	scala V9-PR (platinum) Firmware: 067-6564	5, 9
050-6830-R872		07613389681444	34671	scala V9-PR (sand) Firmware: 067-6564	5, 9
050-6831-P672	07613389BTEV7	07613389681482	34671	scala V-PR trial (platinum) Firmware: 067-6564	5, 9
050-6827-P748	07613389BTEV7	07613389681031	34671	ViO H129 Li (pewter) Firmware: 067-6561	5, 9
050-6827-P648		07613389680997	34671	ViO H129 Li (platinum) Firmware: 067-6561	5, 9
050-6827-R848		07613389681062	34671	ViO H129 Li (sand) Firmware: 067-6561	5, 9
050-6828-P748	07613389BTEV7	07613389681147	34671	ViO H229 Li (pewter) Firmware: 067-6562	5, 9
050-6828-P648		07613389681116	34671	ViO H229 Li (platinum) Firmware: 067-6562	5, 9
050-6828-R848		07613389681178	34671	ViO H229 Li (sand) Firmware: 067-6562	5, 9
050-6829-P748	07613389BTEV7	07613389681260	34671	ViO H329 Li (pewter) Firmware: 067-6563	5, 9
050-6829-P648		07613389681222	34671	ViO H329 Li (platinum) Firmware: 067-6563	5, 9
050-6829-R848		07613389681291	34671	ViO H329 Li (sand) Firmware: 067-6563	5, 9
050-6830-P748	07613389BTEV7	07613389681390	34671	ViO H429 Li (pewter) Firmware: 067-6564	5, 9
050-6830-P648		07613389681352	34671	ViO H429 Li (platinum) Firmware: 067-6564	5, 9

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050-6830-R848		07613389681420	34671	ViO H429 Li (sand) Firmware: 067-6564	5, 9
050-6831-P648	07613389BTEV7	07613389681468	34671	ViO HD29 Li Demo (platinum) Firmware: 067-6564	5, 9
050-6832-P2	07613389BTEV7	07613389653717	34671	Stride V1-UP (amber) Firmware: 067-6565	5, 9
050-6832-P7		07613389654240	34671	Stride V1-UP (pewter) Firmware: 067-6565	5, 9
050-6832-P6		07613389654233	34671	Stride V1-UP (platinum) Firmware: 067-6565	5, 9
050-6832-R8		07613389654257	34671	Stride V1-UP (sand) Firmware: 067-6565	5, 9
050-6833-P2	07613389BTEV7	07613389653724	34671	Stride V3-UP (amber) Firmware: 067-6566	5, 9
050-6833-P8		07613389654295	34671	Stride V3-UP (charcoal) Firmware: 067-6566	5, 9
050-6833-P4		07613389654264	34671	Stride V3-UP (espresso) Firmware: 067-6566	5, 9
050-6833-P7		07613389654288	34671	Stride V3-UP (pewter) Firmware: 067-6566	5, 9
050-6833-P6		07613389654271	34671	Stride V3-UP (platinum) Firmware: 067-6566	5, 9
050-6833-R8		07613389654301	34671	Stride V3-UP (sand) Firmware: 067-6566	5, 9
050-6834-P2	07613389BTEV7	07613389653731	34671	Stride V5-UP (amber) Firmware: 067-6567	5, 9
050-6834-P8		07613389654349	34671	Stride V5-UP (charcoal) Firmware: 067-6567	5, 9
050-6834-P4		07613389654318	34671	Stride V5-UP (espresso) Firmware: 067-6567	5, 9
050-6834-P7		07613389654332	34671	Stride V5-UP (pewter) Firmware: 067-6567	5, 9
050-6834-P6		07613389654325	34671	Stride V5-UP (platinum) Firmware: 067-6567	5, 9
050-6834-R8		07613389654356	34671	Stride V5-UP (sand) Firmware: 067-6567	5, 9
050-6835-P2	07613389BTEV7	07613389653748	34671	Stride V7-UP (amber) Firmware: 067-6568	5, 9
050-6835-P8		07613389654394	34671	Stride V7-UP (charcoal) Firmware: 067-6568	5, 9
050-6835-P4		07613389654363	34671	Stride V7-UP (espresso) Firmware: 067-6568	5, 9
050-6835-P7		07613389654387	34671	Stride V7-UP (pewter) Firmware: 067-6568	5, 9
050-6835-P6		07613389654370	34671	Stride V7-UP (platinum) Firmware: 067-6568	5, 9
050-6835-R8		07613389654400	34671	Stride V7-UP (sand) Firmware: 067-6568	5, 9
050-6836-P2	07613389BTEV7	07613389653755	34671	Stride V9-UP (amber) Firmware: 067-6569	5, 9
050-6836-P8		07613389654448	34671	Stride V9-UP (charcoal) Firmware: 067-6569	5, 9
050-6836-P4		07613389654417	34671	Stride V9-UP (espresso) Firmware: 067-6569	5, 9
050-6836-P7		07613389654431	34671	Stride V9-UP (pewter) Firmware: 067-6569	5, 9
050-6836-P6		07613389654424	34671	Stride V9-UP (platinum) Firmware: 067-6569	5, 9
050-6836-R8		07613389654455	34671	Stride V9-UP (sand) Firmware: 067-6569	5, 9

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050-6837-P6	07613389BTEV7	07613389653762	34671	Stride V-UP FLEX:TRIAL (platinum) Firmware: 067-6569	5, 9
050-6832-P444	07613389BTEV7	07613389657388	34671	Vista V1-UP (espresso) Firmware: 067-6565	5, 9
050-6832-P744		07613389657395	34671	Vista V1-UP (pewter) Firmware: 067-6565	5, 9
050-6832-P644		07613389656442	34671	Vista V1-UP (platinum) Firmware: 067-6565	5, 9
050-6832-R844		07613389657401	34671	Vista V1-UP (sand) Firmware: 067-6565	5, 9
050-6833-P444		07613389657418	34671	Vista V3-UP (espresso) Firmware: 067-6566	5, 9
050-6833-P744	07613389BTEV7	07613389657432	34671	Vista V3-UP (pewter) Firmware: 067-6566	5, 9
050-6833-P644		07613389657425	34671	Vista V3-UP (platinum) Firmware: 067-6566	5, 9
050-6833-R844		07613389657449	34671	Vista V3-UP (sand) Firmware: 067-6566	5, 9
050-6834-P444		07613389657456	34671	Vista V5-UP (espresso) Firmware: 067-6567	5, 9
050-6834-P744	07613389BTEV7	07613389657470	34671	Vista V5-UP (pewter) Firmware: 067-6567	5, 9
050-6834-P644		07613389657463	34671	Vista V5-UP (platinum) Firmware: 067-6567	5, 9
050-6834-R844		07613389657487	34671	Vista V5-UP (sand) Firmware: 067-6567	5, 9
050-6835-P444		07613389657494	34671	Vista V7-UP (espresso) Firmware: 067-6568	5, 9
050-6835-P744	07613389BTEV7	07613389657517	34671	Vista V7-UP (pewter) Firmware: 067-6568	5, 9
050-6835-P644		07613389657500	34671	Vista V7-UP (platinum) Firmware: 067-6568	5, 9
050-6835-R844		07613389657524	34671	Vista V7-UP (sand) Firmware: 067-6568	5, 9
050-6836-P444		07613389657531	34671	Vista V9-UP (espresso) Firmware: 067-6569	5, 9
050-6836-P744	07613389BTEV7	07613389657555	34671	Vista V9-UP (pewter) Firmware: 067-6569	5, 9
050-6836-P644		07613389657548	34671	Vista V9-UP (platinum) Firmware: 067-6569	5, 9
050-6836-R844		07613389657562	34671	Vista V9-UP (sand) Firmware: 067-6569	5, 9
050-6858-P444		07613389656954	34671	Vista V-UP Select (espresso) Firmware: 067-6569	5, 9
050-6858-P744	07613389BTEV7	07613389658934	34671	Vista V-UP Select (pewter) Firmware: 067-6569	5, 9
050-6858-P644		07613389658927	34671	Vista V-UP Select (platinum) Firmware: 067-6569	5, 9
050-6858-R844		07613389658941	34671	Vista V-UP Select (sand) Firmware: 067-6569	5, 9
050-6837-P644	07613389BTEV7	07613389657579	34671	Vista V-UP trial (platinum) Firmware: 067-6569	5, 9
050-6850-U6	07613389BTEV7	07613389655285	34671	beat FS 1-RT675 UP (carbon black) Firmware: 067-6565	5, 9
050-6850-UA		07613389655292	34671	beat FS 1-RT675 UP (cashmere beige) Firmware: 067-6565	5, 9
050-6850-UC		07613389655315	34671	beat FS 1-RT675 UP (metallic anthracite) Firmware: 067-6565	5, 9
050-6850-UB		07613389655308	34671	beat FS 1-RT675 UP (mocha brown)	5, 9

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				Firmware: 067-6565	
050-6850-U4		07613389654691	34671	beat FS 1-RT675 UP (sterling silver) Firmware: 067-6565	5, 9
050-6851-U6		07613389655322	34671	beat FS 3-RT675 UP (carbon black) Firmware: 067-6566	5, 9
050-6851-UA		07613389655339	34671	beat FS 3-RT675 UP (cashmere beige) Firmware: 067-6566	5, 9
050-6851-UC	07613389BTEV7	07613389655353	34671	beat FS 3-RT675 UP (metallic anthracite) Firmware: 067-6566	5, 9
050-6851-UB		07613389655346	34671	beat FS 3-RT675 UP (mocha brown) Firmware: 067-6566	5, 9
050-6851-U4		07613389654707	34671	beat FS 3-RT675 UP (sterling silver) Firmware: 067-6566	5, 9
050-6852-U6	07613389BTEV7	07613389656213	34671	beat FS 5-RT675 UP (carbon black) Firmware: 067-6567	5, 9
050-6852-UA	07613389BTEV7	07613389656220	34671	beat FS 5-RT675 UP (cashmere beige) Firmware: 067-6567	5, 9
050-6852-UC	07613389BTEV7	07613389656244	34671	beat FS 5-RT675 UP (metallic anthracite) Firmware: 067-6567	5, 9
050-6852-UB	07613389BTEV7	07613389656237	34671	beat FS 5-RT675 UP (mocha brown) Firmware: 067-6567	5, 9
050-6852-U4	07613389BTEV7	07613389654714	34671	beat FS 5-RT675 UP (sterling silver) Firmware: 067-6567	5, 9
050-6853-U6		07613389656251	34671	beat FS 7-RT675 UP (carbon black) Firmware: 067-6568	5, 9
050-6853-UA		07613389656268	34671	beat FS 7-RT675 UP (cashmere beige) Firmware: 067-6568	5, 9
050-6853-UC	07613389BTEV7	07613389656282	34671	beat FS 7-RT675 UP (metallic anthracite) Firmware: 067-6568	5, 9
050-6853-UB		07613389656275	34671	beat FS 7-RT675 UP (mocha brown) Firmware: 067-6568	5, 9
050-6853-U4		07613389654721	34671	beat FS 7-RT675 UP (sterling silver) Firmware: 067-6568	5, 9
050-6854-U6		07613389656299	34671	beat FS 9-RT675 UP (carbon black) Firmware: 067-6569	5, 9
050-6854-UA		07613389656305	34671	beat FS 9-RT675 UP (cashmere beige) Firmware: 067-6569	5, 9
050-6854-UC	07613389BTEV7	07613389656329	34671	beat FS 9-RT675 UP (metallic anthracite) Firmware: 067-6569	5, 9
050-6854-UB		07613389656312	34671	beat FS 9-RT675 UP (mocha brown) Firmware: 067-6569	5, 9
050-6854-U4		07613389654738	34671	beat FS 9-RT675 UP (sterling silver) Firmware: 067-6569	5, 9
050-6855-U4	07613389BTEV7	07613389654745	34671	beat FS RT675 UP myChoice (sterling silver) Firmware: 067-6569	5, 9
050-6832-P465		07613389658033	34671	AudioNova V1-UP (espresso) Firmware: 067-6565	5, 9
050-6832-P765		07613389658040	34671	AudioNova V1-UP (pewter) Firmware: 067-6565	5, 9
050-6832-P665	07613389BTEV7	07613389658026	34671	AudioNova V1-UP (platinum) Firmware: 067-6565	5, 9
050-6832-R865		07613389658057	34671	AudioNova V1-UP (sand) Firmware: 067-6565	5, 9
050-6833-P465	07613389BTEV7	07613389658064	34671	AudioNova V3-UP (espresso) Firmware: 067-6566	5, 9

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050-6833-P765		07613389658088	34671	AudioNova V3-UP (pewter) Firmware: 067-6566	5, 9
050-6833-P665		07613389658071	34671	AudioNova V3-UP (platinum) Firmware: 067-6566	5, 9
050-6833-R865		07613389658095	34671	AudioNova V3-UP (sand) Firmware: 067-6566	5, 9
050-6834-P465	07613389BTEV7	07613389652444	34671	AudioNova V5-UP (espresso) Firmware: 067-6567	5, 9
050-6834-P765		07613389652468	34671	AudioNova V5-UP (pewter) Firmware: 067-6567	5, 9
050-6834-P665		07613389652451	34671	AudioNova V5-UP (platinum) Firmware: 067-6567	5, 9
050-6834-R865		07613389652475	34671	AudioNova V5-UP (sand) Firmware: 067-6567	5, 9
050-6835-P465	07613389BTEV7	07613389652482	34671	AudioNova V7-UP (espresso) Firmware: 067-6568	5, 9
050-6835-P765		07613389652505	34671	AudioNova V7-UP (pewter) Firmware: 067-6568	5, 9
050-6835-P665		07613389652499	34671	AudioNova V7-UP (platinum) Firmware: 067-6568	5, 9
050-6835-R865		07613389658217	34671	AudioNova V7-UP (sand) Firmware: 067-6568	5, 9
050-6836-P465	07613389BTEV7	07613389658224	34671	AudioNova V9-UP (espresso) Firmware: 067-6569	5, 9
050-6836-P765		07613389658248	34671	AudioNova V9-UP (pewter) Firmware: 067-6569	5, 9
050-6836-P665		07613389658231	34671	AudioNova V9-UP (platinum) Firmware: 067-6569	5, 9
050-6836-R865		07613389658255	34671	AudioNova V9-UP (sand) Firmware: 067-6569	5, 9
050-6837-P665	07613389BTEV7	07613389658262	34671	AudioNova V-UP trial (platinum) Firmware: 067-6569	5, 9
050-6832-P450	07613389BTEV7	07613389680102	34671	Advance 272 UP (espresso) Firmware: 067-6565	5, 9
050-6832-P750		07613389680126	34671	Advance 272 UP (pewter) Firmware: 067-6565	5, 9
050-6832-P650		07613389680119	34671	Advance 272 UP (platinum) Firmware: 067-6565	5, 9
050-6832-R850		07613389680133	34671	Advance 272 UP (sand) Firmware: 067-6565	5, 9
050-6833-P450	07613389BTEV7	07613389680140	34671	Advance 372 UP (espresso) Firmware: 067-6566	5, 9
050-6833-P750		07613389680164	34671	Advance 372 UP (pewter) Firmware: 067-6566	5, 9
050-6833-P650		07613389680157	34671	Advance 372 UP (platinum) Firmware: 067-6566	5, 9
050-6833-R850		07613389680171	34671	Advance 372 UP (sand) Firmware: 067-6566	5, 9
050-6834-P450	07613389BTEV7	07613389680188	34671	Advance 472 UP (espresso) Firmware: 067-6567	5, 9
050-6834-P750		07613389680201	34671	Advance 472 UP (pewter) Firmware: 067-6567	5, 9
050-6834-P650		07613389680195	34671	Advance 472 UP (platinum) Firmware: 067-6567	5, 9
050-6834-R850		07613389680218	34671	Advance 472 UP (sand) Firmware: 067-6567	5, 9
050-6835-P450	07613389BTEV7	07613389680225	34671	Advance 572 UP (espresso) Firmware: 067-6568	5, 9
050-6835-P750		07613389680249	34671	Advance 572 UP (pewter) Firmware: 067-6568	5, 9

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050-6835-P650		07613389680232	34671	Advance 572 UP (platinum) Firmware: 067-6568	5, 9
050-6835-R850		07613389680256	34671	Advance 572 UP (sand) Firmware: 067-6568	5, 9
050-6836-P450	07613389BTEV7	07613389680263	34671	Advance 672 UP (espresso) Firmware: 067-6569	5, 9
050-6836-P750		07613389680287	34671	Advance 672 UP (pewter) Firmware: 067-6569	5, 9
050-6836-P650		07613389680270	34671	Advance 672 UP (platinum) Firmware: 067-6569	5, 9
050-6836-R850		07613389680294	34671	Advance 672 UP (sand) Firmware: 067-6569	5, 9
050-6837-P650	07613389BTEV7	07613389680300	34671	Advance72 UP trial (platinum) Firmware: 067-6569	5, 9
050-6835-P476	07613389BTEV7	07613389681529	34671	Relate4.0 Gold UP BTE (espresso) Firmware: 067-6568	5, 9
050-6835-P676		07613389681536	34671	Relate4.0 Gold UP BTE (platinum) Firmware: 067-6568	5, 9
050-6835-R876		07613389681543	34671	Relate4.0 Gold UP BTE (sand) Firmware: 067-6568	5, 9
050-6836-P476	07613389BTEV7	07613389681550	34671	Relate4.0 Platinum UP BTE (espresso) Firmware: 067-6569	5, 9
050-6836-P676		07613389681567	34671	Relate4.0 Platinum UP BTE (platinum) Firmware: 067-6569	5, 9
050-6836-R876		07613389681574	34671	Relate4.0 Platinum UP BTE (sand) Firmware: 067-6569	5, 9
050-6833-P476	07613389BTEV7	07613389681499	34671	Relate4.0 Silver UP BTE (espresso) Firmware: 067-6566	5, 9
050-6833-P676		07613389681505	34671	Relate4.0 Silver UP BTE (platinum) Firmware: 067-6566	5, 9
050-6833-R876		07613389681512	34671	Relate4.0 Silver UP BTE (sand) Firmware: 067-6566	5, 9
050-6833-P758	07613389BTEV7	07613389701609	34671	SoniTon UP7 12 UP (pewter) Firmware: 067-6566	5, 9
050-6833-P658		07613389701531	34671	SoniTon UP7 12 UP (platinum) Firmware: 067-6566	5, 9
050-6833-R858		07613389701616	34671	SoniTon UP7 12 UP (sand) Firmware: 067-6566	5, 9
050-6834-P758	07613389BTEV7	07613389701623	34671	SoniTon UP7 16 UP (pewter) Firmware: 067-6567	5, 9
050-6834-P658		07613389701548	34671	SoniTon UP7 16 UP (platinum) Firmware: 067-6567	5, 9
050-6834-R858		07613389701630	34671	SoniTon UP7 16 UP (sand) Firmware: 067-6567	5, 9
050-6835-P758	07613389BTEV7	07613389701647	34671	SoniTon UP7 20 UP (pewter) Firmware: 067-6568	5, 9
050-6835-P658		07613389701555	34671	SoniTon UP7 20 UP (platinum) Firmware: 067-6568	5, 9
050-6835-R858		07613389701654	34671	SoniTon UP7 20 UP (sand) Firmware: 067-6568	5, 9
050-6832-P758	07613389BTEV7	07613389701586	34671	SoniTon UP7 8 UP (pewter) Firmware: 067-6565	5, 9
050-6832-P658		07613389701524	34671	SoniTon UP7 8 UP (platinum) Firmware: 067-6565	5, 9
050-6832-R858		07613389701593	34671	SoniTon UP7 8 UP (sand) Firmware: 067-6565	5, 9
050-6836-P758	07613389BTEV7	07613389701661	34671	SoniTon UP7 Premium UP (pewter) Firmware: 067-6569	5, 9
050-6836-P658		07613389701562	34671	SoniTon UP7 Premium UP (platinum) Firmware: 067-6569	5, 9

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050-6836-R858		07613389701678	34671	SoniTon UP7 Premium UP (sand) Firmware: 067-6569	5, 9
050-6837-P658	07613389BTEV7	07613389701579	34671	SoniTon UP7 UP trial (platinum) Firmware: 067-6569	5, 9

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- FR** (1) Déclaration de conformité UE, (2) Fabricant, (3) Numéro d'enregistrement unique (4) Mandataire, (5) Produits couverts, (6) Voir l'annexe 1, (7) Usage prévu des produits, (8) L'aide auditive a pour fonction d'amplifier les sons et de les transmettre dans l'oreille, afin de compenser une perte auditive, (9) Catégorie de risque des produits (10) Classe IIa ; voir l'annexe 1 pour la règle correspondante, (11) Normes applicables, (12) Spécification commune applicable, (13) Aucune, (14) Certificat CE/organisme notifié, (15) N° 38657 délivré par GMED (0459) (16) Méthode d'évaluation de la conformité, (17) Annexe IV (16) Certificat ISO / organisme de certification, (19) No 32433 (ISO 13485:2016), délivré par GMED, (20) Directive 2014/53/UE, (21) Directive relative aux équipements radio (RED), (22) Directive 2011/65/UE, (23) Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 sur la restriction de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques (refonte), (24) Directive 2015/863/UE, (25) Directive déléguée (UE) 2015/863 de la Commission du 31 mars 2015 modifiant l'annexe II de la directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la liste des substances soumises à limitations (RoHS3), (26) Règlement (CE) n° 1907/2006, (27) Enregistrement, évaluation, autorisation et restriction des substances chimiques (REACH), (28) Directive 2012/19/UE, (29) Directive 2012/19/UE du Parlement européen et du Conseil du 4 juillet 2012 relative aux déchets d'équipements électriques et électroniques (WEEE), (30) Nous, XXX, déclarons par la présente, sous notre seule responsabilité, que les produits répertoriés dans l'annexe 1 sont conformes à la législation détaillée ci-dessus, ainsi qu'au règlement (UE) 2017/745 du Parlement européen et du Conseil relatif aux dispositifs médicaux., (31) Lieu, jour/mois/année, (32) Vice-président de la gestion de la qualité et des affaires réglementaires (33) Responsable des affaires réglementaires, (34) Référence Produit, (35) UDI-DI basique, (36) Nom du produit et version du micrologiciel, (37) Règle de classification Annexe VIII
- ES** (1) Declaración Europea de Conformidad, (2) Fabricante, (3) Número de registro único (4) Representante autorizado, (5) Productos cubiertos, (6) Consulte el anexo 1, (7) Propósito previsto de los productos, (8) El audífono está diseñado para amplificar y transmitir el sonido a los oídos y, de esta forma, compensar la deficiencia auditiva, (9) Clase de riesgo de los productos, (10) Clase IIa, consultar el anexo 1 para ver la norma correspondiente, (11) Normas aplicables, (12) Especificaciones comunes aplicables, (13) Ninguna, (14) Certificado CE/organismo notificado, (15) N.º 38657 expedido por GMED (0459), (16) Línea de evaluación de conformidad, (17) Anexo IV, (18) Certificado ISO/organismo de certificación, (19) N.º 32433 (ISO 13485:2016), emitido por GMED, (20) Directiva 2014/53/UE, (21) Directiva de equipos radioeléctricos (DER), (22) Directiva 2011/65/UE, (23) Directiva 2011/65/UE del Parlamento Europeo y del Consejo, de 8 de junio de 2011, sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos (refundición), (24) Directiva 2015/863/UE, (25) Directiva Delegada (UE) 2015/863 de la Comisión, de 31 de marzo de 2015, por la que se modifica el anexo II de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo en cuanto a la lista de sustancias restringidas (RoHS3), (26) Reglamento (CE) n.º 1907/2006, (27) Reglamento relativo al registro, la evaluación, la autorización y la restricción de las sustancias y preparados químicos (REACH), (28) Directiva 2012/19/UE, (29) Directiva 2012/19/UE del Parlamento Europeo y del Consejo, de 4 de julio de 2012, sobre residuos de aparatos eléctricos y electrónicos (RAEE), (30) Por el presente documento, nosotros, XXX declaramos bajo nuestra propia responsabilidad que los productos enumerados en el anexo 1 cumplen con la legislación mencionada más arriba y el Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo sobre dispositivos médicos., (31) Lugar, día/mes/año, (32) Vicepresidente de Asuntos reguladores y gestión de la calidad, (33) Gestor de Asuntos reguladores, (34) Referencia del producto, (35) UDI-DI Básico, (36) Nombre del producto y versión de firmware, (37) Norma de clasificación Anexo VIII
- DE** (1) EU-Konformitätserklärung, (2) Hersteller, (3) Einmalige Registrierungsnummer (4) Autorisierter Vertreter, (5) Produkte, (6) Siehe Anhang 1, (7) Verwendungszweck der Produkte, (8) Das Hörgerät dient der Verstärkung von Tönen und ihrer Übertragung auf das Ohr, um eine Hörminderung auszugleichen, (9) Risikoklasse der Produkte, (10) Klasse IIa siehe Anhang 1 für die entsprechende Vorschrift, (11) Zutreffende Normen, (12) Zutreffende gemeinsame Spezifikation, (13) Keine, (14) Konformitätsbescheinigung/Benannte Stelle, (15) Nr. 38657 erstellt von GMED (0459), (16) Pfad der Konformitätsbewertung, (17) Anhang IV, (18) ISO-Zertifizierung/Zertifizierungsstelle, (19) Nr. 32433 (ISO 13485:2016), ausgestellt durch GMED, (20) Richtlinie 2014/53/EU, (21) über Funkanlagen (RED), (22) Richtlinie 2011/65/EU, (23) Richtlinie 2011/65/EU des europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (Neufassung), (24) Richtlinie 2015/863/EU, (25) Delegierte Richtlinie (EU) der Kommission 2015/863 vom 31. März 2015 zur Änderung von Anhang II der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates hinsichtlich der Liste der Stoffe, die Beschränkungen unterliegen (RoHS3), (26) Verordnung (EG) Nr. 1907/2006, (27) Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH), (28) Richtlinie 2012/19/EU, (29) Richtlinie 2012/19/EU des europäischen Parlaments und des Rates vom 4. Juli 2012 über Elektro- und Elektronik-Altgeräte (WEEE) (30) Wir, XXX, erklären hiermit in alleiniger Verantwortung, dass die in Anhang 1 aufgeführten Produkte den oben aufgeführten Gesetzen sowie der Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates über Medizinprodukte entsprechen, (31) Ort, TT.MM.JJJJ, (32), VP Quality Management and Regulatory Affairs, (33) Regulatory Affairs Manager, (34) Produkt-referenz, (35) Basis-UDI-DI, (36) Produktname und Firmware-Version, (37) Klassifizierungsregel/Anhang VIII
- PT** (1) Declaração de conformidade da EU, (2) Fabricante, (3) Número único de registo (4) Representante autorizado, (5) Produtos abrangidos, (6) Consultar Anexo 1, (7) Uso previsto dos produtos, (8) O aparelho auditivo destina-se a amplificar e transmitir som ao ouvido e assim compensar a deficiência auditiva, (9) Classe de risco dos produtos, (10) Classe IIa; consultar o Anexo 1 para a regra correspondente, (11) Normas aplicáveis, (12) Especificação comum aplicável, (13) Nenhuma, (14) Certificado CE/Organismo notificado, (15) N.º 38657, emitido pela GMED (0459), (16) Via de avaliação de conformidade, (17) Anexo IV, (18) Certificado ISO/Organismo de certificação, (17) N.º 32433 (ISO 13485:2016), emitido por GMED, (20) Diretiva 2014/53/UE, (21) Diretiva relativa a equipamentos de rádio (RED), (22) Diretiva 2011/65/EU, (23) Diretiva 2011/65/UE do Parlamento Europeu e do Conselho de 8 de junho de 2011 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos (reformulada), (24) Diretiva 2015/863/UE, (25) Diretiva delegada pela Comissão (UE) 2015/863 de 31 de março de 2015 que corrige o Anexo II da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho no que diz respeito à lista de substâncias restritas (RSP3), (26) Regulamento (CE) n.º 1907/2006, (27) Registo, avaliação, autorização e restrição de substâncias químicas (REACH), (28) Diretiva 2012/19/UE, (29) Diretiva 2012/19/UE do Parlamento Europeu e do Conselho de 4 de julho de 2012 relativa aos resíduos de equipamentos elétricos e eletrónicos (REEE), (30) Nós, XXX, sob a nossa exclusiva responsabilidade, declaramos através do presente documento que os produtos enumerados no Anexo 1 estão em conformidade com a legislação acima detalhada e o Regulamento (UE) 2017/745 do Parlamento Europeu e do Conselho relativo a dispositivos médicos, (31) Local, dia-mês-ano, (32) VP de Gestão da Qualidade e Assuntos Regulamentares, (33) Especialista em aspetos legais e regulamentares, (34) Referência do produto, (35) UDI-DI Básica, (36) Nome do produto e versão de firmware, (37) Regra de classificação Anexo VIII.
- IT** (1) Dichiarazione di conformità UE, (2) Produttore, (3) Numero singolo di registrazione, (4) Rappresentante autorizzato, (5) Prodotti interessati, (6) Vedere Allegato 1, (7) Scopo previsto dei prodotti, (8) La funzione dell'apparecchio acustico è quella di amplificare e trasmettere il suono all'orecchio, compensando così la compromissione dell'udito., (9) Classe di rischio dei prodotti, (10) Classe IIa, vedere Allegato 1 per la normativa corrispondente, (11) Standard applicabili, (12) Specifica comune applicabile, (13) nessuna, (14) Certificato CE/ente di certificazione, (15) N° 38657, emesso da GMED (0459), (16) Percorso di valutazione della conformità, (17) Allegato IV, (18) Certificato ISO/Organismo di certificazione, (19) n. 32433 (ISO 13485:2016), rilasciato da GMED, (20) Direttiva 2014/53/UE, (21) Direttiva sulle apparecchiature radio (RED), (22) Direttiva 2011/65/UE, (23) Direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche (riformulata), (24) Direttiva 2015/863/UE, (25) Direttiva Delegata (UE) 2015/863 della Commissione, del 31 marzo 2015, recante modifica dell'Allegato II della Direttiva 2011/65/UE del Parlamento europeo e del Consiglio per quanto riguarda l'elenco delle sostanze con restrizioni d'uso (RoHS3), (26) Regolamento (CE) n. 1907/2006, (27) Registrazione, valutazione, autorizzazione e restrizione delle sostanze chimiche (REACH), (28) Direttiva 2012/19/UE, (29) Direttiva 2012/19/UE del Parlamento europeo e del Consiglio del 4 luglio 2012 sui rifiuti di apparecchiature elettriche ed elettroniche (WEEE), (30) Con la presente XXX, sotto la propria esclusiva responsabilità, dichiara che i prodotti elencati nell'Allegato 1 rispettano le Direttive sopra elencate e il Regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio sui dispositivi medici, (31) Luogo, giorno/mese/anno, (32) VP Controllo qualità e Affari regolatori, (33) Dirigente Affari regolatori, (34) Riferimento prodotto, (35) UDI-DI di base, (36) Nome prodotto e versione firmware, (37) Standard di classificazione Allegato VIII.
- PL** (1) Deklaracja zgodności UE, (2) Producent, (3) Pojedynczy numer rejestracyjny, (4) Autoryzowany przedstawiciel, (5) Produkty, których dotyczy, (6) Patrz Aneks, 1, (7) Przeznaczenie produktów, (8) Aparat słuchowy służy do wzmacniania i przekazywania dźwięku do ucha, a tym samym kompensowania wady słuchu., (9) Klasa ryzyka produktów, (10) Klasa IIa, odpowiednia reguła znajduje się w Załączniku 1, (11) Stosowane standardy, (12) Stosowane specyfikacje ogólne, (13) Brak, (14) Certyfikat WE / jednostka notyfikowana, (15) nr 38657, wydany przez GMED (0459), (16) Metoda oceny zgodności, (17) Aneks IV, (18) Certyfikat ISO/Jednostka certyfikująca, (19) Nr 32433 (ISO 13485:2016), wydany przez GMED, (20) Dyrektywa 2014/53/UE, (21) Dyrektywa w sprawie sprzętu radiowego (Radio Equipment Directive, RED), (22) Dyrektywa 2011/65/UE, (23) Dyrektywa 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym (wersja przekształcona), (24) Dyrektywa 2015/863/UE, (25) Dyrektywa delegowana Komisji (UE) 2015/863 z dnia 31 marca 2015 r. zmieniająca Załącznik II do Dyrektywy Parlamentu Europejskiego i Rady 2011/65/UE w odniesieniu do wykazu substancji objętych ograniczeniami (RoHS3), (26) Rozporządzenie (EC) Nr 1907/2006, (27) Rejestracja, ocena, udzielanie zezwoleń i stosowane ograniczenia w zakresie chemikaliów (REACH), (28) Dyrektywa 2012/19/UE, (29) Dyrektywa 2012/19/UE Parlamentu Europejskiego i Rady z dnia 4 lipca 2012 r. w sprawie zużytego sprzętu elektrycznego i elektronicznego (WEEE), (30) My, XXX, na wyłączną odpowiedzialność niniejszym oświadczamy, że produkty wymienione w Aneksie 1 są zgodne z przepisami prawa wymienionymi powyżej oraz z rozporządzeniem Parlamentu Europejskiego i Rady (UE) 2017/745 w sprawie wyrobów medycznych, (31) Miejscowość, dzień/miesiąc/rok, (32) Wiceprezes ds. zarządzania jakością i regulacji prawnych (33) Kierownik ds. regulacji prawnych; (34) Numer referencyjny produktu, (35) Podstawowy UDI-DI, (36) Nazwa produktu i wersja oprogramowania sprzętowego, (37) Zasada klasyfikacji Aneks VIII
- NL** (1) Europese conformiteitsverklaring, (2) Fabrikant, (3) Registratienummer (SNR), (4) Geautoriseerde vertegenwoordiger, (5) Betrokken producten, (6) Zie Bijlage 1, (7) Beoogd doeleinde van producten, (8) Het doel van hoortoestellen is geluiden te versterken en naar het oor te zenden, en hiermee slechthorendheid te compenseren., (9) Risicoklasse van producten, (10) Klasse IIa zie Bijlage 1 voor de betreffende regel, (11) Toepasselijke normen, (12) Toepasselijke algemene specificatie, (13) Geen, (14) EC-certificaat/Aangemelde instantie, (15) Nr. 38657, verstrekt door GMED (0459), (16) Route van conformiteitsbeoordeling, (17) Bijlage IV, (18) ISO-certificering/Certificerende instantie, (19) Nr. 32433 (ISO 13485:2016), uitgegeven door GMED, (20) Richtlijn 2014/53/EU, (21) Richtlijn radioapparatuur (RED), (22) Richtlijn 2011/65/EU, (23) Richtlijn 2011/65/EU van het Europees Parlement en de Raad van 8 juni 2011

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- betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur (herschikking), (24) Richtlijn 2015/863/EU, (25) Gedelegeerde richtlijn (EU) 2015/863 van de Commissie van 31 maart 2015 tot wijziging van bijlage II bij Richtlijn 2011/65/EU van het Europees Parlement en de Raad wat betreft de lijst van stoffen waarvoor beperkingen gelden (RoHS3), (26) Verordening (EG) nr. 1907/2006, (27) Registratie en beoordeling van en de autorisatie en beperkingen ten aanzien van chemische stoffen (REACH), (28) Richtlijn 2012/19/EU, (29) Richtlijn 2012/19/EU van het Europees Parlement en de Raad van 4 juli 2012 betreffende afgedankte elektrische en elektronische apparatuur (AEEA), (30) Wij, XXX, verklaren hierbij onder volledige verantwoordelijkheid dat de producten vermeld in Bijlage I voldoen aan de hierboven vermelde wetgeving en Verordening (EU) 2017/745 van het Europees Parlement en de Raad inzake medische hulpmiddelen, (31) Locatie, dag/maand/jaar (32) VP Quality Management and Regulatory Affairs, (33) Regulatory Affairs Manager, (34) Product referentie, (35) Basis UDI-DI, (36) Productnaam en firmwareversie, (37) Classificatieregels Bijlage VIII
- BG** (1) ЕС декларация за съответствие, (2) Производител, (3) Единен регистрационен номер, (4) Упълномощен представител, (5) Обхванати продукти, (6) Вижте приложение 1, (7) Предназначение на продукти, (8) Слуховият апарат е предназначен за усилване и предаване на звук до ухото и по този начин за компенсиране на увредения слух., (9) Клас на риска на продуктите, (10) Клас IIa, вижте Приложение 1 за съответното правило, (11) Приложими стандарти, (12) Приложима обща спецификация, (13) Нама, (14) ЕО сертификат/Нотифициран орган, (15) № 38657, издадено от GMED (0459), (16) Подход за оценяване на съответствието, (17) Приложение IV, (18) ISO сертификат/сертифициращ орган, (19) Номер 32433 (ISO 13485:2016), издадено от GMED, (20) Директива 2014/53/ЕС, (21) Директива относно радиосъоръженията (RED), (22) Директива 2011/65/ЕС, (23) Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване (преработена версия), (24) Директива 2015/863/ЕС, (25) Делегирана Директива (ЕС) 2015/863 на Комисията от 31 март 2015 година за изменение на приложението II към Директива 2011/65/ЕС Европейския парламент и на Съвета по отношение на списъка на ограничените вещества (RoHS3), (26) Регламент (ЕО) № 1907/2006, (27) относно регистрацията, оценката, разрешаването и ограничаването на химикали (REACH), (28) Директива 2012/19/ЕС, (29) Директива 2012/19/ЕС на Европейския парламент и на Съвета от 4 юли 2012 г. относно отпадъците от електрическо и електронно оборудване (OEEO), (30) С настоящото ние от XXX декларираме изцяло на наша отговорност, че продуктите, посочени в Приложението 1, са в съответствие с горепосоченото законодателство и с Регламент (ЕО) 2017/745 на Европейския парламент и на Съвета за медицинските изделия. (31) Местоположение, ден/месец/година, (32) Вицепрезидент по управление на качеството и регулаторните въпроси, (33) Ръководител по регулаторни въпроси (34) Справочна информация за продукта, (35) Базово UDI-DI, (36) Наименование на продукта и версия на фирмуера, (37) Правило за класифициране Приложение VIII
- CS** (1) EU Prohlášení o shodě, (2) Výrobce, (3) Jedinečné registrační číslo, (4) Autorizovaný zástupce, (5) Zahrnuté produkty, (6) Viz příloha 1, (7) Zamýšlený účel použití, (8) Sluchadlo je určeno k zesílení a přenosu zvuku do uší, čímž kompenzuje zhoršený sluch., (9) Třída rizika produktů, (10) Odpovídající pravidlo pro třídu IIa viz Příloha 1, (11) Platné normy, (12) Použitelná společná specifikace, (13) Žádná, (14) Certifikát ES/oznamovaný subjekt, (15) č. 38657, vydané společností GMED (0459), (16) Cesta posuzování shody, (17) Příloha IV, (18) Certifikát ISO / certifikáční orgán, (19) č. 32433 (ISO 13485:2016), vydáno GMED, (20) Směrnice 2014/53/EU, (21) o rádiových zařízeních (Radio Equipment Directive, RED), (22) Směrnice 2011/65/EU, (23) Směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních (přepřepované znění), (24) Směrnice 2015/863/EU, (25) Směrnice Komise v přenesené pravomoci (EU) 2015/863 ze dne 31. března 2015, kterou se mění Příloha II Směrnice Evropského parlamentu a Rady 2011/65/EU, pokud jde o seznam omezených látek (RoHS3), (26) Nařízení (ES) č. 1907/2006, (27) Registrace, hodnocení, povolování a omezování chemických látek (REACH), (28) Směrnice 2012/19/EU, (29) Směrnice Evropského parlamentu a Rady 2012/19/EU ze dne 4. července 2012 o odpadních elektrických a elektronických zařízeních (OEEZ), (30) My, XXX, na výhradní odpovědnost tímto prohlašujeme, že produkty uvedené v příloze 1 jsou v souladu s právními předpisy uvedené výše a s nařízením Evropského parlamentu a Rady (EU) 2017/745 o zdravotnických prostředcích, (31) Místo, den/měsíc/rok, (32) VP pro management kvality a regulační záležitosti (33) Manažer pro regulační záležitosti (34) Referenční č. produktu (35) Základní UDI-DI, (36) Název produktu a verze firmwaru, (37) Pravidlo klasifikace Příloha VIII
- DA** (1) EU-overensstemmelseserklæring, (2) Producent, (3) Enkelt registreringsnummer, (4) Autoriseret repræsentant, (5) Omfattede produkter, (6) Se bilag 1, (7) Produktets erklærede formål, (8) Høreapparatet er beregnet til at forstærke og transmittere lyd til øret og dermed kompensere for nedsat hørelse., (9) Produktets risikoklasse, (10) Klasse IIa se bilag 1 for den tilhørende regel, (11) Gældende standarder, (12) Gældende almindelig specifikation, (13) Ingen, (14) EC-certifikat/bemyndiget organ, (15) № 38657, udstedt af GMED (0459), (16) Forløb af overensstemmelsesvurdering, (17) Bilag IV, (18) ISO-certificering/attesterende organ, (19) Nr. 32433 (ISO 13485:2016), udstedt af GMED, (20) Direktiv 2014/53/EU, (21) Direktiv om radioudstyr (RED), (22) Direktiv 2011/65/EU, (23) Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr (omarbejdning), (24) Direktiv 2015/863/EU, (25) Kommissionsdelegeret direktiv (EU) 2015/863 af 31. marts 2015 med ændring af bilag II til Det Europæiske Parlaments og Rådets direktiv 2011/65/EU med hensyn til listen over begrænsede stoffer (RoHS3), (26) Forordning (EF) nr. 1907/2006, (27) Registrering, vurdering, godkendelse og begrænsning af kemikalier (REACH), (28) (27) Direktiv 2012/19/(29) Europa-Parlamentets og Rådets direktiv 2012/19/EU af 4. juli 2012 om affald af elektrisk og elektronisk udstyr (WEEE), (30) Vi, XXX, som eneansvarlig, erklærer hermed, at produkterne i bilag 1 stemmer overens med ovenstående lovgivning og Europa-Parlamentets og Rådets forordning 2017/745/EU om medicinsk udstyr, (31) Lokaltid, dag/måned/år, (32) VP Quality Management og Regulatory Affairs, (33) Regulatory Affairs Manager, (34) Produktreference, (35) Grundlæggende UDI-DI, (36) Produktnavn og firmwareversion, (37) Klassificeringsregel Bilag VIII
- FL** (1) EU-vaatimustenmukaisuusvakuutus, (2) Valmistaja, (3) SRN-numero, (4) Valtuutettu edustaja, (5) Vakuutuksen kohteena olevat tuotteet, (6) Katso liite 1, (7) Tuotteiden käyttötarkoitus, (8) Kuulokoje on tarkoitettu vahvistamaan ja johtamaan ääntä korvaan ja siten kompensoimaan alentunutta kuuloa., (9) Tuotteiden riskiluokka, (10) Luokka IIa katso vastaava sääntö liitteestä 1, (11) Sovellettavat standardit, (12) Sovellettava yleinen eritelmä, (13) Ei mitään, (14) EY-todistus / ilmoitettu laitos, (15) Nro° 38657, myöntäjä: GMED (0459), (16) Vaatimustenmukaisuuden arviointireitti, (17) Liite IV, (18) ISO-sertifikaatti/sertifiointilaitos, (19) Nro 32433 (ISO 13485:2016), myöntäjä: GMED, (20) Direktiivi 2014/53/EU, (21) Radiolaitedirektiivi (RED), (22) Direktiivi 2011/65/EU, (23) Euroopan parlamentin ja neuvoston direktiivi 2011/65/EU, annettu 8 päivänä kesäkuuta 2011, tietytjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa (uudelleenlaadittu), (24) Direktiivi 2015/863/EU, (25) komission delegoitu direktiivi (EU) 2015/863, annettu 31 päivänä maaliskuuta 2015, Euroopan parlamentin ja neuvoston direktiivin 2011/65/EU liitteen II muuttamisesta rajoitusten kohteena olevien aineiden luettelon osalta (RoHS3), (26) Asetus (EY) N:o 1907/2006, (27) Kemikaalien rekisteröinti, arviointi, lupamenettely ja rajoitukset (REACH), (28) Direktiivi 2012/19/EU, (29) Euroopan parlamentin ja neuvoston direktiivi 2012/19/EU, annettu 4 päivänä heinäkuuta 2012, sähkö- ja elektroniikkalaiteromusta (WEEE), (30) XXX yksinomaista vastuullaan vakuuttaa täten, että liitteessä 1 luettellut tuotteet ovat edellä mainittujen lakien ja lakisäntälististä laitteista annettun Euroopan parlamentin ja neuvoston asetuksen (EU) 2017/745 mukaisia., (31) Paikka, päivä/kuukausi/vuosi, (32) Laadunhallinnan ja sääntelyasioiden apulaisjohtaja (33) Sääntelyasioiden päällikkö, (34) Tuotteen viite, (35) Laitemallin UDI-DI, (36) Tuotteen nimi ja laiteohjelmiston versio, (37) Luokitussääntö Liite VIII
- EL** (1) Δήλωση συμμόρφωσης ΕΕ, (2) Κατασκευαστής, (3) Ενιαίος αριθμός καταχώρισης, (4) Εξουσιοδοτημένος αντιπρόσωπος, (5) Καλυπτόμενα προϊόντα, (6) Βλ. Παράρτημα 1, (7) Ενδεδειγμένος σκοπός των προϊόντων, (8) Το ακουστικό βαρηκοΐας προορίζεται για ενίσχυση και μετάδοση ήχου στο αυτί, σε περιπτώσεις όπου η ακοή είναι περιορισμένη., (9) Κατηγορία κινδύνου προϊόντων, (10) Κατηγορία IIa βλ. Παράρτημα 1 για τον αντίστοιχο κανόνα., (11) Εφαρμοστέα πρότυπα, (12) Εφαρμοστέα κοινή προδιαγραφή, (13) Καμία, (14) Πιστοποιητικό ΕΚ/Κοινοποιημένος φορέας, (15) Αρ. 38657, φορέας έκδοσης GMED (0459), (16) Διαδικασία αξιολόγησης της συμμόρφωσης, (17) Παράρτημα IV, (18) Πιστοποιητικό ISO/Φορέας πιστοποίησης, (19) Αρ. 32433 (ISO 13485:2016), φορέας έκδοσης GMED, (20) Οδηγία 2014/53/ΕΕ, (21) Οδηγία σχετικά με τον ραδιοεξοπλισμό (RED), (22) Οδηγία 2011/65/ΕΕ, (23) Οδηγία 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 για τον περιορισμό της χρήσης ορισμένων επικινδυνών ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό (αναθεώρηση), (24) Οδηγία 2015/863/ΕΕ, (25) Κατ' εξουσιοδότηση οδηγία (ΕΕ) 2015/863 της 31ης Μαρτίου 2015 της Επιτροπής για την τροποποίηση του Παραρτήματος II της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου όσον αφορά τον κατάλογο των ουσιών που υπόκεινται σε περιορισμό (RoHS3), (26) Κανονισμός (ΕΕ) με Αρ. 1907/2006, (27) Καταχώριση, αξιολόγηση, αδειοδότηση και περιορισμοί των χημικών προϊόντων (REACH), (28) Οδηγία 2012/19/ΕΕ, (29) Οδηγία 2012/19/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 4ης Ιουλίου 2012 για τα απόβλητα ηλεκτρικού και ηλεκτρονικού εξοπλισμού (WEEE), (30) Εμείς, η XXX, με αποκλειστική ευθύνη, δηλώνουμε δια του παρόντος ότι τα προϊόντα που παρατίθενται στο Παράρτημα 1 συμμορφώνονται με την ανωτέρω αναφερόμενη νομοθεσία και τον κανονισμό (ΕΕ) 2017/745 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου για τα ιατροτεχνολογικά προϊόντα., (31) Τοποθεσία, ημέρα/μήνας/έτος, (32) Αντιπρόεδρος διαχείρισης ποιότητας και ρυθμιστικών θεμάτων, (33) Διευθυντής ρυθμιστικών θεμάτων, (34) Αναγνωριστικό Προϊόντος, (35) Βασικό UDI-DI, (36) Ονομα προϊόντος και έκδοση υλικολογισμικού, (37) Κανόνας ταξινόμησης Παράρτημα VIII
- HR** (1) EU izjava o sukladnosti, (2) Proizvođač, (3) Jedinstveni registracijski broj (4) Ovlaštení zastupnik, (5) Obuhvaćeni proizvodi, (6) Pogledajte Prilog 1, (7) Namjena proizvoda, (8) Namjena je slušnog pomagala da pojača i prenese zvuk do uha i na taj način kompenzira oštećenje sluha., (9) Klasa rizika proizvoda, (10) II.a klasa, pogledajte Prilog 1. za odgovarajuće pravilo., (11) Primjenjive norme, (12) Primjenjive opće specifikacije, (13) Nema, (14) EZ potvrda / prijavljeno tijelo, (15) br. 38657, izdalo društvo GMED (0459), (16) Postupak ocjenjivanja sukladnosti, (17) Prilog IV, (18) Certifikat ISO / certifikacijsko tijelo, (19) Br. 32433 (ISO 13485:2016), izdalo društvo GMED, (20) Direktiva 2014/53/EU, (21) Direktiva o radijskoj opremi (RED), (22) Direktiva 2011/65/EU, (23) Direktiva 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi (preinačeno), (24) Direktiva 2015/863/EU, (25) Delegirana direktiva Komisije (EU) 2015/863 od 31. ožujka 2015. o izmjeni Priloga II. Direktivi 2011/65/EU Europskog parlamenta i Vijeća u pogledu popisa ograničenih tvari (RoHS3), (26) Uredba (EZ) br. 1907/2006, (27) Registracija, evaluacija, autorizacija i ograničavanje kemikalija (REACH), (28) Direktiva 2012/19/EU, (29) Direktiva 2012/19/EU Europskog parlamenta i Vijeća od 4. srpnja 2012. o otpadnoj električnoj i elektroničkoj opremi (OEOO), (30) Mi, XXX pod vlastitom odgovornošću, ovime izjavljujemo da su proizvodi navedeni u Prilogu 1. sukladni s prethodno navedenim propisima i Uredbom (EU) 2017/745 Europskog parlamenta i Vijeća o medicinskim proizvodima, (31) Mjesto, dan/mjesec/godina, (32) Potpredsjednik za upravljanje kvalitetom i regulatorna pitanja, (33) Voditelj regulatornih poslova, (34) Upućivanje na proizvod (35) Osnovni UDI-DI, (36) Naziv proizvoda i inačica firmvera, (37) Pravilo razvrstavanja Prilog VIII

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- HU** (1) EU-megfelelőségi nyilatkozat, (2) Gyártó, (3) Egyedi regisztrációs szám, (4) Meghatalmazott képviselő, (5) Érintett termékek, (6) Lásd 1. melléklet, (7) Termékek rendeltetése, (8) A hallókészülék a hang felerősítésére és a fülbe való továbbítására szolgál, így kompenzálva a halláskárosodást., (9) Termékek kockázati besorolása, (10) IIa. osztály, a vonatkozó szabály az 1. mellékletben olvasható, (11) Vonatkozó szabványok, (12) Vonatkozó egységes előírások, (13) Nincsenek, (14) EK-nyilatkozat / Bejelentett szervezet, (15) a 38657, GMED által kibocsátva (0459), (16) Megfelelőségértékelés módja, (17) IV. melléklet, (18) ISO-tanúsítvány / tanúsító szervezet, (19) száma: 32433 (ISO 13485:2016), kiadta: GMED, (20) 2014/53/EU irányelv, (21) Rádióberendezésekre vonatkozó irányelv (RED), (22) 2011/65/EU irányelv, (23) Az Európai Parlament és Tanács 2011. június 8-án kiadott 2011/65/EU irányelvével egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról (átdolgozás), (24) 2015/863/EU jelű irányelv, (25) A Bizottság (EU) 2015/863 felhatalmazáson alapuló irányelvével (2015. március 31.) a 2011/65/EU jelű európai parlamenti és tanácsi irányelv II. mellékletének a korlátozott anyagok jegyzéke tekintetében történő módosításáról (RoHS3), (26) 1907/2006-os számú (EK) rendelet, (27) Vegyi anyagok regisztrálása, értékelése, engedélyezése és korlátozása (REACH), (28) 2012/19/EU irányelv, (29) Az Európai Parlament és Tanács 2012. július 4-én kiadott 2012/19/EU irányelvével az elektromos és elektronikus berendezések hulladékairól (WEEE), (30) A(z) XXX kizárólagos felelősséggel kijelenti, hogy az 1. mellékletben felsorolt termékek megfelelnek a fent részletezett jogszabályoknak, valamint az Európai Parlament és a Tanács orvostechnikai eszközökről szóló (EU) 2017/745 rendeletének., (31) Helység, év/hónap/nap, (32) Minőségirányításért és szabályozásügyért felelős alelnök (33) Szabályozási ügyekért felelős vezető, (34) Termék-hivatkozás , (35) Alapvető UDI-DI, (36) Terméknév és firmware-verzió, (37) Osztályozási szabály VIII. Melléklet
- LT** (1) ES atitikties deklaracija, (2) Gamintojas, (3) Unikalus registracijos numeris, (4) Įgaliojasis atstovas, (5) Gaminiai, kuriems taikoma, (6) Žr. 1 priedą, (7) Numatyta gaminių paskirtis, (8) Klausos aparatas skirtas stiprinti ir perduoti garsą į ausį ir taip kompensuoti klausos sutrikimus., (9) Gaminių rizikos klasė, (10) Atitinkama IIa klasės taisyklė žr. 1 priede., (11) Taikomi standartai, (12) Taikomos bendrosios specifikacijos, (13) Nėra, (14) EB sertifikatas / notifikuoti įstaiiga, (15) N° 38657, išdavė GMED (0459) , (16) Atitikties vertinimo būdas, (17) IV priedo , (18) ISO sertifikatas / sertifikavimo įstaiiga, (19) Nr. 32433 (ISO 13485:2016), išduotas GMED, (20) Direktyva 2014/53/ES, (21) Radijo įrenginių direktyva (RID), (22) Direktyva 2011/65/ES, (23) 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyva 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo (nauja redakcija), (24) Direktyva 2015/863/ES, (25) 2015 m. kovo 31 d. Komisijos deleguotąją direktyvą (ES) 2015/863 iš dalies keičiamas Europos Parlamento ir Tarybos direktyvos 2011/65/ES II priedas, susijęs su ribojamų medžiagų sąrašu (RoHS3), (26) Reglamentas (EB) Nr. 1907/2006, (27) Cheminių medžiagų registracija, įvertinimas, autorizacija ir apribojimai (REACH), (28) Direktyva 2012/19/ES, (29) 2012 m. liepos 4 d. Europos Parlamento ir Tarybos direktyva 2012/19/ES dėl elektros ir elektroninės įrangos atliekų (WEEE), (30) Mes, „XXX“, prisiimdami visą atsakomybę pareiškiamo, kad 1 priede išvardyti gaminiai atitinka pirmiau paminėtus teisės aktus ir Europos Parlamento ir Tarybos reglamentą (ES) 2017/745 dėl medicinos priemonių, (31) Vieta, metalinio-diena, (32) Kokybės valdymo ir reguliavimo reikalų viceprezidentas, (33) Reguliavimo reikalų vadovas (34) Gaminio nuoroda, (35) Bazinis UDI-DI, (36) Gaminio pavadinimas ir aparatinės įrangos versija, (37) Klasifikavimo taisyklė VIII priedas
- LV** (1) EK atbilstības deklarācija, (2) Ražotājs, (3) Vienotais reģistrācijas numurs (4) Pilnvarotais pārstāvis, (5) Ietvertie produkti, (6) Skatīt 1. pielikumu, (7) Produktu pielietojuma mērķis, (8) Dzirdes aparāts ir paredzēts, lai pastiprinātu un pārraidītu skaņu uz ausi, kompensējot dzirdes traucējumus., (9) Produktu riska klasifikācija, (10) IIa klase; attiecīgo noteikumu skatīt 1. pielikumā, (11) Piemērojamie standarti, (12) Spēkā esošās standarta specifikācijas, (13) Nav, (14) EK sertifikāts/pilnvarotā iestāde, (15) N° 38657, izdevējs: GMED (0459), (16) Atbilstības novērtēšanas avots, (17) IV pielikuma , (18) ISO sertifikāts/sertifikācijas iestāde, (19) N° 32433 (ISO 13485:2016), izsniedza GMED, (20) Direktīva 2014/53/ES, (21) Radioiekārtu direktīva (RAD), (22) Direktīva 2011/65/ES, (23) Eiropas Parlamenta un Eiropas Padomes 2011. gada 8. jūnija Direktīva 2011/65/ES par dažu bīstamu vielu izmantošanas ierobežošanu elektriskajās un elektroniskajās iekārtās (pārstrādāta redakcija), (24) Direktīva 2015/863/ES, (25) Komisijas deleģētā direktīva (ES) 2015/863 2015. gada 31. martā pievienots II pielikums direktīvai 2011/65/ES, ko pieņēmis Eiropas Parlaments un Padome attiecībā uz aizliegto vielu sarakstu (RoHS3), (26) Regula (EK) Nr. 1907/2006, (27) Ķīmikāliju reģistrēšana, vērtēšana, licencēšana un ierobežošana (REACH), (28) Direktīva 2012/19/ES, (29) Eiropas Parlamenta un Eiropas Padomes 2012. gada 4. jūlija Direktīva 2012/19/ES par elektrisko un elektronisko iekārtu atkritumiem (EELIA), (30) XXX, uzņemoties pilnu atbildību, apliecina, ka 1. pielikumā norādītie izstrādājumi atbilst iepriekšminēto normatīvo aktu un Eiropas Parlamenta un Padomes Regulas (ES) 2017/745 par medicīniskām ierīcēm prasībām, (31) Atrašanās vieta/diena/mēnesis/gads, (32) Kvalitātes vadības un regulatīvo jautājumu nodaļas priekšsēdētāja vietnieks (33) Regulatīvo jautājumu nodaļas vadītājs, (34) Produkta atsauces Nr, (35) Pamata UDI-DI, (36) Izstrādājuma nosaukums un aparātu programmatūras versija, (37) Klasifikācijas noteikumi VIII pielikums
- RO** (1) Declarație de conformitate, (2) Producător, (3) Număr unic de înregistrare (4) Reprezentant autorizat, (5) Produse care fac obiectul declarației, (6) Consultați Anexa 1, (7) Domeniul de utilizare a produselor, (8) Aparatul auditiv este conceput pentru a amplifica și transmite sunetul către ureche, compensând în acest mod deficiențele de auz., (9) Clasa de risc, (10) Clasa IIa Consultați Anexa 1 pentru norma corespunzătoare, (11) Standarde aplicabile, (12) Specificație comună aplicabilă, (13) Nu există, (14) Certificat CE/Organism notificat, (15) Nr. 38657, emis de GMED (0459) , (16) Procedura de evaluare a conformității, (17) Anexa IV, (18) Certificat ISO/Organism de certificare, (19) Nr. 32433 (ISO 13485:2016), eliberat de GMED, (20) Directiva 2014/53/UE, (21) Directiva referitoare la echipamentele radio (RED), (22) Directiva 2011/65/UE, (23) Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice (reformare), (24) Directiva 2015/863/UE, (25) Directiva delegată (UE) 2015/863 a Comisiei din 31 martie 2015 de modificare a anexei II la Directiva 2011/65/UE a Parlamentului European și a Consiliului în ceea ce privește lista substanțelor restricționate (RoHS3), (26) Regulamentul (CE) nr. 1907/2006, (27) Înregistrarea, evaluarea, autorizarea și restricționarea substanțelor chimice (REACH), (28) Directiva 2012/19/UE, (29) Directiva 2012/19/UE a Parlamentului European și a Consiliului din 4 iulie 2012 privind deșeurile de echipamente electrice și electronice (DEEE), (30) Subscrisa, XXX, declarăm prin prezenta, pe propria răspundere, faptul că produsele enumerate în Anexa 1 sunt în conformitate cu legislația specificată mai sus și cu Regulamentul (UE) 2017/745 al Parlamentului European și al Consiliului privind dispozitivele medicale, (31) Locul, ziua/luna/anul, (32) Vicepreședinte managementul calității și reglementări, (33) Manager reglementare, (34) Referință produs, (35) UDI-DI De bază, (36) Denumire produs și versiune de firmware , (37) Regulă de clasificare Anexa VIII
- SK** (1) Vyhlásenie o zhode EÚ, (2) Výrobca, (3) Jediné registračné číslo, (4) Autorizovaný zástupca, (5) Dotknuté výrobky, (6) Pozri Dodatok 1, (7) Účel, na ktorý sú výrobky určené, (8) Tento načúvací prístroj slúži na zosilnenie zvuku a jeho prenos do uší osôb so zhoršeným sluchom, ktoré vďaka tomu môžu lepšie počuť., (9) Riziková trieda výrobkov, (10) Trieda Ila, pozri prílohu 1 pre príslušné pravidlo, (11) Platné normy, (12) Platné spoločné technické parametre, (13) Žiadne, (14) Osvedčenie ES/Notifikovaný orgán , (15) Č. 38657, vydal: GMED (0459), (16) Spôsob posúdenia zhody, (17) Dodatok IV, (18) ISO certifikát/Certifikačný orgán, (19) Č. 32433 (ISO 13485:2016), vydal GMED, (20) Smernica 2014/53/EÚ , (21) Smernica o rádiových zariadeniach (RED), (22) Smernica 2011/65/EÚ, (23) Smernica Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach (prepracované znenie), (24) Smernica 2015/863/EÚ, (25) delegovaná smernica Komisie (EÚ) 2015/863 z 31. marca 2015, ktorou sa mení príloha II k smernici Európskeho parlamentu a Rady 2011/65/EÚ, pokiaľ ide o zoznam obmedzených látok (RoHS3), (26) Nariadenie (ES) č. 1907/2006, (27) Registrácia, hodnotenie, autorizácia a obmedzovanie chemických látok (REACH), (28) Smernica 2012/19/EÚ, (29) Smernica Európskeho parlamentu a Rady 2012/19/EÚ zo 4. júla 2012 o odpade z elektrických a elektronických zariadení (WEEE), (30) My, spoločnosť XXX, týmto na vlastnú zodpovednosť vyhlasujeme, že výrobky uvedené v Dodatku 1 sú v súlade s vyššie uvedenými právnymi predpismi a nariadením Európskeho parlamentu a Rady (EÚ) 2017/745 o zdravotníckych pomôckach., (31) Miesto, deň/mesiac/rok(32) riadenie kvality VP a regulačné záležitosti, (33) vedúci pre regulačné záležitosti, (34) Referencia výrobku, (35) Základné UDI-DI, (36) Názov výrobku a verzia firmvéru, (37) Klasifikačné pravidlo Dodatok VIII
- SL** (1) Izjava o skladnosti EU, (2) Proizvajalec, (3) Enotna registrska številka, (4) Pooblaščen predstavnik, (5) Zajeti izdelki, (6) Glejte prilogo 1, (7) Predvideni namen izdelkov, (8) Namen slušnega aparata je ojačati in oddajati zvok v ušesa in s tem izravnati okvarjen sluh., (9) Razred tveganja izdelkov, (10) Razred Ila, za zadevno pravilo si oglejte Prilogo 1, (11) Uporabljeni standardi, (12) Uporabljene skupne specifikacije, (13) Brez, (14) Certifikat ES/Priglašeni organ , (15) št. 38657, izdan s strani GMED (0459), (16) Pot ugotavljanja skladnosti, (17) Priloga IV, (18) Certifikat ISO/certifikacijski organ, (19) št. 32433 (ISO 13485:2016), izdan s strani GMED, (20) Direktiva 2014/53/EU, (21) Direktiva o radijski opremi (RED), (22) Direktiva 2011/65/EU, (23) Direktiva 2011/65/EU Evropskega parlamenta in Sveta z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi (prenovitev), (24) Direktiva 2015/863/EU, (25) Delegirana direktiva Komisije (EU) 2015/863 z dne 31. marca 2015 o spremembi Priloge II k Direktivi 2011/65/EU Evropskega parlamenta in Sveta v zvezi s seznamom omejenih snovi (RoHS3), (26) Uredba (ES) št. 1907/2006, (27) Registracija, evalvacija, avtorizacija in omejevanje kemikalij (REACH), (28) Direktiva 2012/19/EU, (29) Direktiva 2012/19/EU Evropskega parlamenta in Sveta z dne 4. julija 2012 o odpadni električni in elektronski opremi (OEEEO), (30) Mi, XXX, pod izključno odgovornostjo izjavljamo, da so izdelki, navedeni v Prilogi 1, skladni z zakonodajo, podrobneje navedeno zgoraj, in Uredbo (EU) 2017/745 Evropskega parlamenta in Sveta o medicinskih pripomočkih, (31) Lokacija, dan/mesec/leto, (32) Podpredsednik oddelka za kakovost in zakonodajo, (33) Vodja regulativnih zadev, (34) Referenca izdelka, (35) Osnovni UDI-DI, (36) Ime izdelka in različica strojne programske opreme , (37) Pravilo razvrstitve Priloga VIII
- SV** (1) EU-överensstämmelsedeklaration, (2) Tillverkare, (3) Enskilt registreringsnummer, (4) Auktoriserad representant, (5) Produkter som deklarerationen täcker, (6) Se Bilaga 1, (7) Produkternas avsedda användning, (8) Namen slusnega aparata je ojačati in oddajati zvok v ušesa in s tem izravnati okvarjen sluh., (9) Riskklassificering av produkterna, (10) Klass Ila se Bilaga 1 för motsvarande regel, (11) Tillämpliga standarder, (12) Tillämplig allmän specifikation, (13) Ingen, (14) ES-certifikat/annmält organ, (15) N° 38657, utfärdat av GMED (0459), (16) Metod för att bedöma efterlevnad, (17) Bilaga IV, (18) ISO-certifiering/Certifierande enhet, (19) Nr 32433 (ISO 13485:2016), utfärdat av GMED, (20) Direktiv 2014/53/EU, (21) Radioutrustningsdirektivet (RED), (22) Direktiv 2011/65/EU, (23) Europaparlamentets och Rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning (omarbetning), (24) Direktiv 2015/863/EU, (25) Kommissionens delegerade Direktiv (EU) 2015/863 av den 31 mars 2015 om ändring av bilaga II i Europaparlamentets och rådets direktiv 2011/65/EU vad gäller förteckningen av ämnen som omfattas av begränsningar (RoHS3), (26) Förordning (EG) nr 1907/2006, (27) Registrering, utvärdering, godkännande och begränsning av kemikalier (REACH), (28) Direktiv 2012/19/EU, (29) Europaparlamentets och Rådets direktiv 2012/19/EU av den 4 juli 2012 om avfall som utgörs av eller innehåller elektrisk och elektronisk utrustning (WEEE), (30) Vi, XXX, intygar under eget ansvar härmed att de produkter som anges i Bilaga 1 överensstämmer med den

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lagstiftning som nämns ovan och Europaparlamentets och Rådets förordning (EU) 2017/745 om medicintekniska produkter. , (31) Ort, dag/månad/år, (32) VP Quality Management and Regulatory Affairs (33) Regulatory Affairs Manager, (34) Produktreferens, (35) Grundläggande UDI-DI, (36) Produktnamn och firmware-version, (37) Klassificeringsregel Bilaga VIII

ET (1) EL-i vastavustunnistus, (2) Tootja, (3) Unikaalne registrikood, (4) Volitatud esindaja, (5) Deklaratsiooniga hõlmatud tooted, (6) Vt lisa 1, (7) Toodete sihtotstarve, (8) Kuuldeaparaat on ette nähtud heli võimendamiseks ja edastamiseks kõrvadesse ning seeläbi kuulmiskahjustuse kompenseerimiseks. , (9) Toote riskiklass, (10) Klass IIa vt vastava reegli lisa 1, (11) Kohaldatavad standardid, (12) Kohaldatav ühine spetsifikatsioon, (13) Puudub, (14) EÜ sertifikaat / teavitatud asutus, (15) N° 38657, väljastaja GMED (0459), (16) vastavushindamistee, (17) Lisa IV, (18) ISO sertifikaat / sertifitseerimisasutus, (19) nr 32433 (ISO 13485:2016), väljaandja GMED, (20) Direktiiv 2014/53/EL, (21) Raadioseadmete direktiiv (RED), (22) Direktiiv 2011/65/EL, (23) Euroopa Parlamendi ja nõukogu 8. juuni 2011 direktiiv 2011/65/EL teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes (ümbesõnastatud), (24) Direktiiv 2015/863/EL, (25) Komisjoni delegeeritud direktiiv (EL) 2015/863 31. märtsist 2015, mis muudab Euroopa Parlamendi ja Nõukogu direktiivi 2011/65/EL lisa II piiratud ainete loendi osas (RoHS3), (26) Määrus (EÜ) nr 1907/2006, (27) Kemikaalide registreerimine, hindamine, autorseerimine ja piiramine (REACH), (28) Direktiiv 2012/19/EL, (29) Euroopa Parlamendi ja nõukogu 4. juuli 2012. aasta direktiiv 2012/19/EL elektri- ja elektroonikaseadmetest tekkinud jäätmete (elektroonikaromude) kohta (WEEE), (30) Meie, XXX, deklareerime ainuvastutuse juures käesolevaga, et lisa 1 loetletud tooted vastavad ülaltoodud seadusandlusele ning Euroopa Parlamendi ja nõukogu määrusele (EL) 2017/745 meditsiiniseadmete kohta. , (31) Koht, päev/kuu/aasta, (32) Asepresident kvaliteedi ja regulatiivküsimuste alal, (33) Juht regulatiivküsimuste alal, (34) Toote viide, (35) Põhi-UDI-DI, (36) Toote nimi ja püsivara versioon, (37) Klassifitseerimiseeskiri Lisa VIII

GA (1) Dearbhú Comhréireachta AE, (2) Monaróir, (3) Cláruimhir Aonarach, (4) Ionadaí údaraithe, (5) Táirgí a chuimsítear, (6) Féach larscríbhinn 1, (7) Cuspóir bheartaithe na dtáirgí, (8) Is é is aidhm leis an áis éisteachta fuaim a mhéadú agus a tharchur chuig an gcluas agus, ar an gcaoi sin, lagáisteacht a chúiteamh., (9) Aicme riosca na dtáirgí, (10) Aicme IIa féach Aguisín 1 le haghaidh na rialach a bhaineann, (11) Caighdeán in infheidhme, (12) Sonraíocht choiteann in infheidhme, (13) Ní ann do shonraíocht, (14) Comhlacht dá dtugtar fógra maidir le Dearbhú CE, (15) Uimh. 38657, eistithe ag GMED (0459), (16) Bealach measúnaithe comhréireachta, (17) larscríbhinn IV, (18) Deimhniú ISO / Comhlacht deimhniúcháin, (19) Uimh. 32433 (ISO 13485:2016), arna eisiúint ag GMED, (20) Treoir 2014/53/AE (21) Treoir maidir le Trealamh Raidió (RED), (22) Treoir 2011/65/AE, (23) Treoir 2011/65/AE ó Pharlaimint na hEorpa agus ón gComhairle an 8 Meitheamh 2011 maidir le srian ar shubstaintí guaiseacha áirithe a úsáid i dtrealamh leictreach agus leictreonach (ateilgthe), (24) Treoir 2015/863/EU, (25) Treoir Tharmilgthe ón gCoimisiún (AE) 2015/863 ar an 31 Márta 2015 a leasaíonn Aguisín II de Threoir 2011/65/EU de Pharlaimint na hEorpa agus den Chomhairle maidir le liosta na substaintí teoranta (RoHS3), (26) Rialachán (CE) Uimh. 1907/2006, (27) Clárú, Meastóireacht, Údarú agus Srianadh Ceimiceán (REACH), (28) Treoir 2012/19/AE, (29) Treoir 2012/19/AE ó Pharlaimint na hEorpa agus ón gComhairle an 4 Iúil 2012 maidir le dramhthrealamh leictreach agus leictreonach (DTLL), (30) Dearbhaímid, XXX faoi fhreagracht aonair, leis seo go bhfuil na táirgí a liostaítear in larscríbhinn 1 i gcomhréir leis an reachtaíocht a shonraítear thuas agus le Rialachán (AE) 2017/745 ó Pharlaimint na hEorpa agus ón gComhairle maidir le feistí leighis, (31) Áit, lá/mí/bliain, (32) VP Bainistíocht Cáilíochta agus Gnóthaí Rialála, (33) Bainisteoir Gnóthaí Rialála, (34) Tagairt an táirge, (35) SF-SFU bunúsach, (36) Ainm an táirge agus leagan Dochtearraí, (37) Riall aicmiúcháin larscríbhinn VIII

MT (1) Dikjarazzjoni ta' Konformità tal-UE, (2) Manifattur, (3) Numru ta' Registrazzjoni Uniku, (4) Rappreżentant Awtorizzat, (5) Prodotti koperti, (6) Ara l-Anness 1, (7) Skop maħsub tal-prodotti, (8) L-apparat ta' ghajjnuna għa-smiġ huwa intiż biex jamplifika u jitttrażmetti hoss lill-widna u għalhekk jikkompensa għal indeboliment fis-smiġ., (9) Klassi ta' riskju tal-prodotti, (10) Klassi IIa ara l-Anness 1 għar-regola korrispondenti, (11) Standards applikabbli, (12) Speċifikazzjoni komuni applikabbli, (13) Xejn, (14) Korp Ċertifikat/Notifikat tal-KE, (15) Nru 38657, maħruġ minn GMED (0459), (16) Rotta tal-Valutazzjoni tal-Konformità, (17) L-Anness IV, (18) Ċertifikat/Korp ta' Ċertifikazzjoni tal-ISO, (19) N° 32433 (ISO 13485:2016), maħruġ minn GMED, (20) Id-Direttiva 2014/53/UE, (21) Id-Direttiva dwar it-Tagħmir tar-Radju (RED), (22) Id-Direttiva 2011/65/UE, (23) Id-Direttiva 2011/65/UE tal-Parlament Ewropew u tal-Kunsill tat-8 ta' Gunju 2011 dwar ir-restrizzjoni tal-użu ta' ċerti sustanzi perikolużi fit-tagħmir elettriku u elettroniku (riformulazzjoni), (24) Id-Direttiva 2015/863/UE, (25) Id-Direttiva Delegata tal-Kummissjoni (UE) 2015/863 tal-31 ta' Marzu 2015 li temenda l-Anness II tad-Direttiva 2011/65/UE tal-Parlament Ewropew u tal-Kunsill fir-rigward tal-lista ta' sustanzi restritti (RoHS3), (26) Ir-Regolament (KE) Nru 1907/2006, (27) Ir-Registrizzjoni, il-Valutazzjoni, l-Awtorizzazzjoni u r-Restrizzjoni ta' Sustanzi Kimiċi (REACH), (28) Id-Direttiva 2012/19/UE, (29) Id-Direttiva 2012/19/UE tal-Parlament Ewropew u tal-Kunsill tal-4 ta' Lulju 2012 dwar skart ta' tagħmir elettriku u elettroniku (WEEE), (30) Ahna, XXX taħt responsabbiltà unika, b'dan niddikjaraw li l-prodotti elenkati fl-Anness 1 huma konformi mal-leġiżlazzjoni spjegata hawn fuq, u r-Regolament (UE) 2017/745 tal-Parlament Ewropew u tal-Kunsill dwar apparati mediċi, (31) Post, jum/xahar/sena, (32) VP Gestiġni tal-Kwalità u Affarijiet Regolatorji, (33) Maniġer tal-Affarijiet Regolatorji (34) Referenza tal-Prodott, (35) UDI-DI Bażiku, (36) Isem il-Prodott u Verżjoni tal-firmware, (37) Regola ta' Klassifikazzjoni Anness VIII

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Type: QDL

Document No.: QDL-2756

Rev.: 3

Title: MDR DoC uPrince2/3

Process: Regulatory Affairs

Owner: 53HPARMAR Harleen Parmar

Status: CURRENT

Effective Date: 13-Feb-2024

Attributes

Attribute Type	Value	Description
Affected Site	5300	Kitchener (CA)
Project	uPrince 2/3	

Approvals

Level	Actor	Job Title	Sign-off Date	Sign-off By
1	Bryan Hynes	Coordinator, Information Control	05-Feb-2024	53BHYNES
2	Blathnaid Feldman	VP Quality Management and Regulatory Affairs	06-Feb-2024	11BFELDMAN
2	David Sooprayen	Interim Head of RA	13-Feb-2024	22DSOOPRAYEN

Revision Notes

Access Activity	Note	Accessed By	Accessed Date
Remark	Updated to add all uPrince3 BTE-UP devices.	53HPARMAR	05-Feb-2024