MDR DoC Roger NeckLoop

EU Declaration of Conformity

Manufacturer:	Sonova AG, Laubisrütistrasse 28, 8712 Stäfa, Switzerland
Single Registration Number:	CH-MF-000015958
Authorised Representative:	Sonova Deutschland GmbH, Max-Eyth-Straße 20, 70736 Fellbach, Germany
Single Registration Number:	DE-AR-000006322
Products covered:	See Annex 1
Products intended purpose:	The intended purpose of Roger NeckLoop is to provide hearing aid users wireless access to an external sound source.
Products risk class:	MDR: Class I, see Annex 1 for the corresponding rule RED: Class 2, operation at frequencies below 9 kHz
Applicable standards:	EN 60601-1-2 EN 60601-1 ISO 20417 EN 62366-1 EN ISO 14971 EN 60601-1-6 EN ISO 10993-1 EN 62304 EN ISO 15223-1 EN 300 328 V2.2.2 EN 301 489-1 V2.2.3 EN 301 489-3 V2.1.1 EN 301 489-17 V3.2.4 Draft ETSI EN 300 422-4 V2.1.2.0.0.3 EN 62479
Applicable common specification:	None
Conformity Assessment Route:	Annex II & III
ISO Certificate/Certifying Body:	N° 32433 (ISO 13485:2016), issued by GMED
Directive 2014/53/EU	Annex III, EU type-examination certificate No. CE T818822N-01-TEC (modules B and C) issued by CTC advanced GmbH, Untertuerkheimer Str. 6-10., 66117 Saarbruecken, Germany. Notified Body Number: 0682
Directive 2011/65/EU	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)**
Directive 2015/863/EU	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)**
Regulation (EC) No. 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (***REACH***)
Directive 2012//19/EU	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment **(WEEE)**

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.

Stäfa, (Switzerland) 26/01/2022
Location, day/month/year

Glenn Borrett
Senior Regulatory Affairs Manager

Fellbach, (Germany) 26/01/2022
Location, day/month/year

Bente-Iris Eller
Quality & Regulatory Manager

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Annex 1

Product Reference	2014/53/EU Compliant ?	Basic UDI-DI	UDI-DI	GMDN	Product Name	Classification Rule Annex VIII
056-4004-P5210	Yes	076133890564004FX	07613389388602	57961	Roger NeckLoop (02) (champagne)	I,13
056-4004-P52103	Yes		07613389392098	57961	Roger NeckLoop (02) Demo (w/o plug)	I,13
056-4004-P5211	Yes		07613389392067	57961	Roger NeckLoop (02) (US, champagne)	I,13
056-4004-P5212	Yes		07613389392074	57961	Roger NeckLoop (02) (EU, champagne)	I,13
056-4005-P5110	Yes	076133890564005FZ	07613389400830	57961	Roger NeckLoop (03) (champagne)	I,13
056-4005-P5111	Yes		07613389398946	57961	Roger NeckLoop (03) (US, champagne)	I,13
056-4005-P51118	Yes		07613389398953	57961	Roger NeckLoop (03) (US, champagne)	I,13
056-4005-P5112	Yes		07613389398960	57961	Roger NeckLoop (03) (EU, champagne)	I,13