MDR DoC Charger Case Go

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 charger is used to charge the rechargeable hearing aids, and to carry the hearing aids when not being worn.
Products risk class:	MDR: Class I, see Annex 1 for the corresponding rule RED: Class 2
Applicable standards:	EN 60601-1-2 EN 60601-1 EN ISO 20417 IEC 62366-1 EN ISO 14971 EN 60601-1-6 EN ISO 10993-1 EN 62304 EN ISO 15223-1 EN 60601-1-11:2015 EN 301 489-1 V2.2.0 EN 301 489-3 V2.1.1 EN ETSI 303 417 V1.1.1
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. G0M-2012-9542-V01 issued by Eurofins Product Service GmbH, Storkower Str. 38c, 15526 Reichenwalde, Germany. Notified Body Number: 0681
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) 08/04/2022
Location, day/month/year

Glenn Borrett
Director Regulatory Affairs

Fellbach, (Germany) 08/04/2022
Location, day/month/year

Bente-Iris Eller
Quality & Regulatory Manager

Annex 1

to EU Declaration of Conformity

Product Reference	**Basic UDI-DI**	**UDI-DI**	**GMDN**	**Product Name**	**Classification Rule** Annex VIII
075-3017-10	076133890753017GG	07613389329216	17115	Phonak Charger Case Go	I,13
075-3017-11		07613389329995	17115	Phonak Charger Case Go (US plug)	I,13
075-3017-12		07613389330007	17115	Phonak Charger Case Go (EU plug)	I,13