



GQ-RPT-05498 EU MDR Declaration of Conformity
Product Brand: StarLink (Starkey)
Product Family: Hearing Aid Accessories

GQ-RPT-05498
Revision 5.0

Legal Manufacturer	Starkey Laboratories, Inc., 6700 Washington Avenue South, Eden Prairie, MN., USA 55344
Legal Manufacturer Single Registration Number (SRN)	SRN: US-MF-000014382
EU Authorised Representative	Starkey Laboratories (Germany) G.m.b.H Weg beim Jäger 218 – 222 22335 Hamburg, Germany
EU Authorised Representative Single Registration Number (SRN)	SRN: DE-AR-000010831
Medical Device Classification and GMDN	Please refer to Appendix A for Device Classification and GMDN
Product Name	Please refer to Appendix A for product or trade name.
Intended Purpose	Refer to GQ-RPT-05497
Product Codes / Product Range and Description	Refer to Appendix A
Basic UDI-DI	Refer to Appendix A
Technical Documentation Number	GQ-RPT-05497
Common Specifications	N/A
Declaration Statement	Starkey Laboratories, Inc. declares under sole responsibility that the following products are in conformity with the European Regulation 2017/745 and follows relevant Union Regulation.
MDR Conformity Assessment Pathway	Starkey Laboratories, Inc. declares under sole responsibility that the following products are in conformity with the European Regulation 2017/745 of 05 April 2017 following the provisions of Annex IX, excluding assessment of the technical documentation (Chapter 2). Compliance of the designated products with the "general safety and performance requirements" of Annex I of the European Regulation 2017/745 has been certified by: Starkey Laboratories, Inc. 6700 Washington Avenue South Eden Prairie, MN 55344 USA Technical Documentation File: GQ-RPT-05497

Signature	
Name	Brian Dahl
Title/Position	Vice President of Quality and Regulatory



Location of DoC Signed	Eden Prairie, MN, USA
Date DoC Signed	05-Oct-2023

Declaration of Conformity Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
1.0	DCR-02583: Initial Release	T. Burrell	24JUN2022
2.0	DCR-03035: Update to BUDI-DI, add programmer	T. Burrell	28JUL2022
3.0	Adding Hearing Aid Accessories Remote Control 2.0 and StarLink Standard and Custom chargers 2.0 under Yellowstone program	Manasa Boppana	27-Sep-2023
4.0	Revision of Name and Brand from Starkey to StarLink. Expansion of charger	Manasa Boppana	29-Sep-2023
5.0	Added EU Risk classification Rule 13 and updated EMDN code that are applicable for accessories	Manasa Boppana	05-Oct-2023

Appendix A: Hearing Aid Product Range and Description

Product Name	Device Style / Device Type	Basic UDI-DI	EMDN	GMDN	EU Risk Class
StarLink Mini Turbo Charger	Hearing Aid Accessory	0842318143017TW	Y214580	17115	Rule 1, Rule 13, Class I
StarLink TV Streamer	Hearing Aid Accessory	0842318143005TP	Y214580	41243	Rule 1, Rule 13, Class I
StarLink Remote	Hearing Aid Accessory	0842318143011TJ	Y214580	57885	Rule 1, Rule 13, Class I
StarLink Remote Microphone +	Hearing Aid Accessory	0842318143006TR	Y214580	57886	Rule 1, Rule 13, Class I
StarLink Mini Remote Microphone	Hearing Aid Accessory	0842318143006TR	Y214580	57886	Rule 1, Rule 13, Class I
StarLink Premium Standard Charger	Hearing Aid Accessory	0842318143084TQ	Y214580	17115	Rule 1, Rule 13, Class I
StarLink Premium Custom Charger	Hearing Aid Accessory	0842318143084TQ	Y214580	17115	Rule 1, Rule 13, Class I
StarLink SurfLink Programmer	Hearing Aid Accessory	0842318179025W8	Y214580	57884	Rule 1, Rule 13, Class I
StarLink Remote Control 2.0	Hearing Aid Accessory	0842318143011TJ	Y214580	57885	Rule 1, Rule 13, Class I
StarLink Charger 2.0 (mRIC R)	Hearing Aid Accessory	0842318143084UD	Y214580	17115	Rule 1, Rule 13, Class I
StarLink Charger 2.0 (RIC RT)	Hearing Aid Accessory	0842318143084UD	Y214580	17115	Rule 1, Rule 13, Class I



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Product Name	Device Style / Device Type	Basic UDI-DI	EMDN	GMDN	EU Risk Class
StarLink Custom Charger 2.0	Hearing Aid Accessory	0842318143084UD	Y214580	17115	Rule 1, Rule 13, Class I