



Hear better. Live better.

GQ-RPT-08420: EU Declaration of Conformity

Starkey
Genesis AI

GQ-RPT-08420

Revision 3.0

Legal Manufacturer	Starkey Laboratories, Inc., 6700 Washington Avenue South, Eden Prairie, MN., USA 55344
Legal Manufacturer Single Registration Number (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)	DE-AR-000010831
Medical Device Classification and EMDN/GMDN	Hearing aid products are classified as Class IIa (Rule 9) Accessories are classified as Class I (Rule 1) Please refer to Appendix A for Device Classification, and EMDN/GMDN
Notified Body	These products are subjected to examination by the British Standards Institute (Notified Body Number 2797) Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Phone: +31 (0)20 346 07 80
Certificate Information	MDR 760129 ISO 13485 – FM91716
Product Name	Refer to Appendix A
Intended Purpose	An air conduction hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. The Multiflex Tinnitus Technology is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients suffering from tinnitus.
Product Codes / Product Range and Description	Refer to Appendix A
Basic UDI-DI	Refer to Appendix A
Technical Documentation Number	GQ-RPT-07867
Common Specifications	N/A



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MDR 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	<p>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 Chapter 1 and Chapter 3 for Class IIa devices, and Annex II & Annex III for Class I devices.</p> <p>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:</p> <p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Tel: +31 20 346 0780 Web: www.bsigroup.com NB #2797</p>

Signature	
Name	Brian Dahl
Title/Position	VP of Quality and Regulatory
Place of Issue	Eden Prairie, MN
Date of Issue	31. OCT. 2023

Declaration of Conformity Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
01	Initial Release	Ann Moua	31 AUG 2023
02	Addition of RIC312	Brian Dahl	See Grand Avenue
03	Addition of CIC 312	Manasa Boppana	See Grand Avenue



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Appendix A: Hearing Aid Product Range and Description

Product Name and Technology Tier	Device Style / Device Type	Basic UDI-DI	EMDN	GMDN	EU Risk Class
Starkey Genesis AI 12 CIC NW	Completely-In-Canal (CIC) Hearing Aid	0842318172047UZ	Y2145060203	41209	Class IIa
Starkey Genesis AI 16 CIC NW					
Starkey Genesis AI 20 CIC NW					
Starkey Genesis AI 24 CIC NW					
Starkey Genesis AI 24 IIC NW	Invisible-In-Canal (IIC) Hearing Aid	0842318172047UZ	Y2145060204	41209	Class IIa
Starkey Genesis AI 20 IIC NW					
Starkey Genesis AI 16 IIC NW					
Starkey Genesis AI 24 ITE R					
Starkey Genesis AI 20 ITE R	In-the-Ear (ITE) Hearing Aid	0842318172047UZ	Y2145060201	34672	Class IIa
Starkey Genesis AI 16 ITE R					
Starkey Genesis AI 12 ITE R					
Starkey Genesis AI 24 ITC R					
Starkey Genesis AI 20 ITC R	In-the-Canal (ITC) Hearing Aid	0842318172047UZ	Y2145060201	41209	Class IIa
Starkey Genesis AI 16 ITC R					
Starkey Genesis AI 12 ITC R					
Starkey Genesis AI 24 HS R					
Starkey Genesis AI 20 HS R	Half-Shell (HS) Hearing Aid	0842318172047UZ	Y214506	34672	Class IIa
Starkey Genesis AI 16 HS R					
Starkey Genesis AI 12 HS R					
Starkey Genesis AI 24 RIC RT					
Starkey Genesis AI CROS RIC RT	Receiver-In-Canal (RIC) Hearing Aid	0842318163191V5	Y2145060102	47169	Class IIa
Starkey Genesis AI 20 RIC RT					
Starkey Genesis AI 16 RIC RT					
Starkey Genesis AI 12 RIC RT					
Starkey Genesis AI 24 mRIC R	Receiver-In-Canal (RIC) Hearing Aid	0842318163191V5	Y2145060102	47169	Class IIa
Starkey Genesis AI 20 mRIC R					
Starkey Genesis AI 16 mRIC R					
Starkey Genesis AI 12 mRIC R					
STARKEY GENESIS AI 24 RIC 312	Receiver-In-Canal (RIC) Hearing Aid	0842318163191V5	Y2145060102	47169	Class IIa
STARKEY GENESIS AI 20 RIC 312					
STARKEY GENESIS AI 16 RIC 312					
STARKEY GENESIS AI 12 RIC 312					
STARKEY GENESIS AI 24 CIC	Completely-In-Canal (CIC) Hearing Aid	0842318172047UZ	Y2145060203	41209	Class IIa
STARKEY GENESIS AI 20 CIC					
STARKEY GENESIS AI 16 CIC					
STARKEY GENESIS AI 12 CIC					