

## UK-RPT-06478: EU Declaration of Conformity SoundGear Starkey SoundGear, SoundScope

UK-RPT-06478 Revision 4.0

Legal Manufacturer	Starkey Laboratories, ltd., William F Austin House, Pepper Road, Hazel Grove, Stockport. SK7 5BX United Kingdom.  On behalf of: Starkey Laboratories Inc., 6600 Washington Avenue South, Eden Prairie, MN, 55344	
EU Authorised Representative	Starkey Laboratories (Germany) G.m.b.H  Weg beim Jäger 218-222 22335 Hamburg, Germany	
Product Names	SoundGear Work SoundScope Pro-Tect SoundGear Sport SoundScope Pro-Tect i-Hunt	
Declaration Statement	Starkey Laboratories ltd. declares under sole responsibility that the products listed above are in conformity with the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment, and where such is the case, with the national standard transposing harmonized standards EN 352-7:2002 and EN 352-2:2002.	
	The PPE meets the essential health and safety requirements set out in Annex II, which apply to it when used for its intended purpose.	
	The notified body (BSI 2797) performed the EU Type examination (Module B) and the PPE is subject to the conformity assessment procedure: Conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body (BSI 2797).	
	Subject to the procedure set out in Article 47 of Regulation (EU) 2016/425 under the supervision of the notified body (BSI 2797).	
Certificate Information	CE 709922: EU Type Examination Certificate In respect of: Level Dependent Ear plugs to EN 352-7:2002 and EN 352-2:2002	
	CE 707261: Conformity to Type based on Quality Assurance of the Production process in respect of: Module D – Hearing Protection Devices	

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Notified Body	These products are subjected to examination by the British Standards Institute (Notified Body Number 2797)		
	Address:	BSI Group, The Netherlands B.V. Say Building, John M Keynesplein 9 1066 EP Amsterdam, Netherlands +31 (0)20 346 07 80	
Technical Documentation Number	UK-RPT-03	578	

Signature	PAPA
Name	Brian Dahl
Title/Position	Sr Director of Quality
Date	8.29.2022

## Declaration of Conformity Revision History:

Revision	Summary of Changes / Additions	Created / Revised by	Date
Number			
01	Initial Release	Megan Bernier	24 June 2019
02	Addition of "SoundGear Sport" and "SoundGear Work" names.	Liz Hignett	24 September 2019
03	Addition of BSI address	Liz Hignett	17 March 2020
04	Addition of ref. to EN 352-2:2002, Reformatting and initial release in Grand Ave.	Matthew Fletcher	15 August 2022

## Appendix A: Hearing Aid Product Range and Description:

Product Name and Technology Tier	Device Style / Device Type	EU Risk Category
SoundGear Work SoundScope Pro-Tect,	In the Ear Custom Moulded Level Dependent Ear Plugs	III
SoundGear Sport SoundScope Pro-Tect i-Hunt,	In the Ear Custom Moulded Level Dependent Ear Plugs	Ш

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