



DEVICE DETAILS

NAME OF DEVICE	STARKEY EDGE AI IN-THE-EAR HEARING AIDS
ESTABLISHMENT NAME	BEST HEARING AID CENTRE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB5867525-218172
BRAND NAME	STARKEY
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Edge AI Hearing Aid Systems are air conduction Hearing Aids. Input to the device is in the form of sound waves, which are converted by a microphone to an electronic signal. This electronic signal is digitally processed utilizing digital signal processing (DSP) technology. The signal is amplified and shaped by internal DSP circuitry and firmware algorithms to compensate for the patient's hearing loss. The resultant signal is converted to an acoustic output and presented to the patient's ear canal.
DEVICE INTENDED PURPOSE	Air conduction hearing aids are wearable sound-amplifying devices that are 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.
VALIDITY DATE OF REGISTRATION	01/12/2025 - 30/11/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	STARKEY EDGE AI 24 CIC	72096-SHT
2	STARKEY EDGE AI 20 CIC	72097-SHT
3	STARKEY EDGE AI 16 CIC	72098-SHT
4	STARKEY EDGE AI 12 CIC	72099-SHT
5	STARKEY EDGE AI 24 ITC R	72128-SHT
6	STARKEY EDGE AI 20 ITC R	72129-SHT
7	STARKEY EDGE AI 16 ITC R	72130-SHT
8	STARKEY EDGE AI 12 ITC R	72131-SHT
9	Starkey Edge AI 24 ITE R	72121-SHT

NO	NAME OF DEVICE	IDENTIFIER
10	Starkey Edge AI 20 ITE R	72123-SHT
11	Starkey Edge AI 16 ITE R	72124-SHT
12	Starkey Edge AI 12 ITE R	72125-SHT
13	STARKEY EDGE AI 24 HS R	72132-SHT
14	STARKEY EDGE AI 20 HS R	72134-SHT
15	STARKEY EDGE AI 16 HS R	72135-SHT
16	STARKEY EDGE AI 12 HS R	72136-SHT



MEDICAL DEVICE AUTHORITY