SGS

EC Certificate Full Quality Assurance System: Certificate US03/58708

The management system of

## Magnatone Hearing Aid Corporation dba Persona Medical

170 North Cypress Way, Casselberry, FL, 32707, United States

has been assessed and certified as meeting the requirements of

## **Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

For the following products

Pre-Wires;

Behind-The-Ear (BTE), Mini BTE Hearing Aids;

In-The-Ear (ITE) Stock Hearing Aids;

Receiver in Canal (RIC) Hearing Aids;

Behind-the Ear/On-the-Ear (BTE/OTE) Hearing Aids;

On-the-Ear (OTE) Hearing Aids;

Receiver in Canal (RIC) Hearing Aids

Behind-The Ear, On-The-Ear, Receiver in Canal Hearing Aids: Tinnitus

Vlaske

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 08 January 2019 until 24 March 2020 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 14 March 2018 Issue 10. Certified since 24 March 2003

Certification is based on reports numbered WW/MC 208283

Authorised by



## SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215

Page 1 of 1





This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-dients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.