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;
On-The-Ear & Receiver in Canal (OTE/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 Maskers.

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 13 March 2016 until 24 March 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 March 2018
Issue 9. Certified since 24 March 2003

Certification is based on reports numbered WW/ME 208283

Authorised by

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