Lloyd's Register
LRQA

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Puretone Limited
9-10 Henley Business Park,
Trident Close, Medway City Estate,
Rochester, Kent
United Kingdom

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	LRQ 0953101/B
Original Approval:	3 February 1997
Current Certificate:	1 February 2018
Certificate Expiry:	31 January 2021

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE CERTIFICATE LRQ 0953101/B SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

Puretone Limited
9-10 Henley Business Park,
Trident Close, Medway City Estate,
Rochester, Kent
United Kingdom

Class IIa Products

Behind the Ear (BTE) Hearing Aids
In the Ear (ITE) Hearing Aids
In the Canal (ITC) Hearing Aids
Completely in the Canal (CIC) Hearing Aids
Tinnitus System
Inductive Earpieces
Standard Earmoulds
Face Plate Kits

Schedule Issue: 01

Date of Schedule Issue: 1 February 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

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