



CERTIFICATE OF REGISTRATION

This is to certify that

Unitron Hearing Ltd.

20 Beasley Drive, PO Box 9017, Kitchener, Ontario N2G 4X1 Canada

Refer to Attachment to Certificate of Registration dated May 30, 2013 for additional certified sites

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2003

for the following scope of registration

The registration covers the Quality Management System for the design, manufacture and service of behind the ear and in the ear hearing instruments. Design of hearing aid fitting software.

Certificate No.: CERT-0070942
File No.: 002705

Original Date: July 28, 1995
Effective Date: May 27, 2013
Expiry Date: May 26, 2016

Chris Jouppi
President,
QMI-SAI Canada Limited

Guillaume Gignac, ing.f
Vice President, Corporate Operations, Accreditation & Quality
QMI-SAI Canada Limited



ISO 13485



CMDCAS Recognized Registrar



Registered by:

SAI Global Certification Services Pty Ltd, 286 Sussex Street, Sydney NSW 2000 Australia with SAI Global, 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.
To verify that this certificate is current, please refer to the SAI Global On-Line Certification Register: www.qmi-saiglobal.com/qmi_companies/



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ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No: CERT-0070942 issued on May 30, 2013

File No.

002705

Unitron Hearing Ltd.

20 Beasley Drive, PO Box 9017, Kitchener, Ontario N2G 4X1 Canada

Processes covered at 20 Beasley Drive: Design, manufacture, service, repair, management, quality, sales, marketing and purchasing processes.

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Unitron Hearing - Kitchener

250 Trillium Drive, Kitchener, Ontario N2E 1X2 Canada

Dependent pocesses covered at 250 Trillium Drive: Warehouse and distributing processes.

These registrations are dependent on Unitron Hearing Ltd. (File No. 002705) maintaining their scope of registration to ISO 13485:2003



EC Certificate

Certificate Number: DGM - 046

This is to certify that the quality system of:

Unitron Hearing Ltd.
20 Beasley Drive, P.O. Box 9017
Kitchener ON N2G 4X1,
Canada

has been approved in conformity with the requirements of:


Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

**Design, manufacture and final inspection of
 BTE hearing instrument systems, of ITE hearing instrument systems,
 of ITE hearing aid kits and of related accessories in class IIa**

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.


Carsten Worm Jensen
 Authorized person

For Presafe Denmark A/S

Date of issue: 2015-06-08
 Expires: 2018-06-07
 Initial date of issue: 1997-09-19
 Reference: Aur2a1404v410f015



Presafe Denmark A/S
Notified Body, Identification No. 0543
 Tuborg Parkvej 8, 2900 Hellerup, Denmark

DGM