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

Tel. 519.895.0100
Fax. 519.895.0108
Toll-free 877.492.6244

unitron.com

Kitchener, Ontario, Canada

Declaration of Conformity

Hearing Instrument System Accessory: uDirect 3

Year of Manufacture: March 2015 onwards

We, Unitron Hearing , hereby declare under our own responsibility that the medical device Class 1 mentioned above, is in conformity with essential requirements of the Medical Device Directive 93/42/ECC (MDD) Annex 1 and with the applicable provisions and other relevant requirements of the R&TTE Directive 1999/5/EC (Radio and Telecommunications Terminal Equipment). This product is in conformity with the following standards and/or other standardizing documents:

Safety	IEC 60601-1:2005 +Cor.1:2006 +Cor.2:2007 +A1:2012
	EN 60601-1:2006 +Cor.2010
	IEC 60950-1:2005 2ed +A1:2009 +A2:2013
	EN 60950-1:2006 +A11:2009 +A1:2010 + AC:2011 + A12:2011
EMC	EN 60601-1-2:2007 + Cor:2010
	EN 301 489-1 v1.9.2:2011 EN 301 489-3 v1.6.1:2013
	EN 301 489-17 2.2.1:2012
Radio Spectrum	EN 300 330-1 v1.7.1:2010 EN 300 330-2 v1.5.1:2010
	EN 300 328 V1.8.1: 2012
Health	IEC 62479:2010

This declaration is supported by:

Certificate of approval, Certificate Number: 0027235 to quality standards ISO 9001:2008 and ISO 13485:2003, issued by QMI.

Kitchener, Dated: 25-Nov-2015

Ara Talaslian
Vice President,
Research & Development

Brian Matcheski
Manager,
Quality Assurance