



20 Beasley Drive Kitchener, ON
 Canada N2E 1Y6
 Tel. 519.895.0100
 Fax. 519.895.0108
 Toll-free 877.492.6244
unitron.com



EC Declaration of Conformity MDD 93/42/EEC

We, Unitron Hearing, a division of National Hearing Services Inc., located at 20 Beasley Dr., Kitchener, ON, Canada, N2E 1Y6, **declare under our sole responsibility that the following BTE, ITE, ITE Kits, or Fitting Software:**

Unitron Civic	Vista	AudioNova
Shine Rev+ P	Vista Basic+ P 13	AN Basic+ P 13
Shine Rev+ M	Vista Basic+ M 312	AN Basic+ M 312
Shine Rev+ UP	Vista Basic+ UP 675	AN Basic+ UP 675
Shine Rev+ RIC	Vista Basic+ R 312	AN Basic+ R 312
Shine Rev+ W 13 Dir	Vista Basic+ W 13 Dir	AN Basic+ W 13 Dir
Shine Rev+ W 312 Dir	Vista Basic+ W 312 Dir	AN Basic+ W 312 Dir
Shine Rev+ 10A Omni	Vista Basic+ 10A Omni	AN Basic+ 10A Omni

Device Classification: *I/a*

Notified Body: Presafe Denmark A/S

CE Certificate Number: DGM-046

Authorized Representative: *Sonova AG, Laubisrütistrasse 28, CH-8712, Stäfa, Switzerland*

are in conformity with the requirements of the Council Directive MDD 93/42/EEC,

based upon compliance of the products with the following standards:

EN 60601-1-2	EN 60601-2-66	EN 62304	EN ISO 13485	EN ISO 10993-1	EN ISO 10993-5	EN ISO 15223-1	EN ISO 10993-10
EN 60601-1	EN 62366	EN 60118-13	EN ISO 14971	EN ISO 1041	EN ISO 10993-18	EN ISO 10993-12	

Date placed the first CE marking on the market: [April 01 2020](#)

[Kitchener, ON, Mar 27 2020](#)

Signed electronically via SmartSolve
Ara Talaslian
 Vice President, R&D

Signed electronically via SmartSolve
Craig Horsman
 Senior Manager, Quality Assurance