DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

Manufacturer: **Bernafon AG**
Morgenstrasse 131, CH-3018 Bern, Switzerland
Telephone +41 31 998 15 15

Products:
Brand: Bernafon
Family: Leox
Models: Leox 7 (LX7) BTE SP, Leox 3 (LX3) BTE SP
Styles: BTE SP

The Manufacturer declares under its sole responsibility that the listed hearing aid models and styles are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

Radio Equipment Directive 2014/53/EU with applied Medical Device Directive MDD 93/42/EEC standards and council recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz).

Standard(s) Applied in Full:
Health and Safety Article 3.1a:

EN 62479:2010
EN 60601-1:2006 + Cor: 2006 + A1:2013
EN 60601-1-6:2010 + A1:2015 / EN 62366:2008 + A1:2015
IEC 60601-2-66:2015 / Draft EN 60601-2-66:2018

Electromagnetic Compatibility (EMC) Article 3.1b:

Draft EN 301 489-1 v.2.2.0
EN 301 489-3 v.2.1.1
Draft EN 301 489-17 v.3.2.0
EN 60601-1-2:2016 / IEC 60601-1-2:2014
IEC 60118-13:2011

Radio Spectrum Matters Article 3.2:

EN 300 328 v.2.1.1
EN 300 330 v.2.1.1
EN 300 422-4 v.2.1.1 with the use of NSH 7th edition (Telecoil)

Testing performed by CTC advanced GmbH, Untertürkheimer Strasse 6–10; 66117 Saarbrücken, Germany.
RED directive conformity assessment by Bernafon AG.

CE 0543

Signed on behalf of Bernafon AG, 2019-08-15.

Asif Muhammad

Asif Muhammad
Director, Regulatory Affairs

bernafon
Your hearing · Our passion