

EC - Declaration of Conformity

Manufacturer: GN Hearing A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark

Conformity Assessment Procedure: Annex VII of Medical Device Directive (MDD)
93/42/EEC
Annex II of Radio Equipment Directive (RED)
2014/53/EU

Identification of the Device: **Category:** Accessory
Type: Wireless Remote Control
Brand: Generic
Model: Remote Control 3
RC-3

GMDN: 57885

Declaration of Conformity expiry date: 23-12-2022

Classification of the Device (MDD): Class I, Rules 1 and 12, MDD 93/42/EEC

Applied standards and normative standards:

MDD: EN 62368-1:2017, EN 60601-1-2:2015, EN ISO 10993-1:2018, EN ISO 14971:2012, EN 62304:2006/AC:2008, EN 62366:2008, EN ISO 15223-1:2016;

RED: Health & Safety: EN 62368-1:2017, EN 62479:2010,
EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0,
Spectrum: EN 300 328 V2.1.1;

RoHS: EN 50581:2012, EN 62321-1:2013

We, the manufacturer hereby declare that the above-mentioned devices comply with the relevant provisions of the EU Council Directive 93/42/EEC (MDD) Annex I - Essential Requirements and the relevant provisions of the EU Council Directive 2014/53/EU (RED) Article 3 - Essential Requirements and their relevant transpositions into national laws of the Member States in which the above-mentioned devices are distributed.

Place and Date: Ballerup, 29-11-2019



Christina Molt-Wengel
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