

EC – Declaration of Conformity

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

Conformity Assessment Procedure: Annex II of Medical Device Directive (MDD) 93/42/EEC
Annex III of Radio and Telecommunications Terminal Equipment (R&TTE) 1999/5/EC

Identification of Notified Body (MDD): DQS Medizinprodukte GmbH
August-Schanz-Str. 21,
D-60433 Frankfurt am Main, Germany
Notified Body EC Code No. 0297

Identification of EC-certificate (MDD): DQS Certificate No. 283130 MR2

Identification of the Device: **Category:** Hearing Aid
Type: Behind-The-Ear
Brand: Beltona
Model: First Family
FI1763-DRW, FI1763-DRPW,
FI1763-DRSW, FI1763-DRUW
FI963-DRW, FI963-DRPW,
FI963-DRSW, FI963-DRUW

GMDN code: 47169

Revision: Report No. 229

Declaration of Conformity expiry date: 2016-12-31

Classification of the Device (MDD): Class IIa, Rule 9, MDD 93/42/EEC

Applied standards and normative standards:
US: ANSI 63.19-2011, IEC 60601-1-2:2007
MDD: IEC 60118-0:83+A1:94, IEC 60118-7:2005, IEC 60118-13:2011,
ISO 10993-5:2009, ISO 10993-10:2010, ISO 14971:2007, IEC 60601-2-66:2012
R&TTE: IEC 60601-2:66:2012, EN/(IEC) 62311:2008 (Health & Safety)
EN 301 489-17 2.1.1 (EMC), EN 300-328 V1.7.1 (Spectrum)

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 essential requirements and other relevant requirements of the R&TTE Directive 1999/5/EC and their relevant transpositions into national laws of the Member States in which the above mentioned medical devices are distributed.

Place and Date: Ballerup, 28 January 2014


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