

EC – Declaration of Conformity

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| Manufacturer: | Beltone 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 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: Beltone Model: True Family TRU1766DW, TRU966DW, TRU666DW |
| | Revision: Report No. 179 |
| Classification of the Device (MDD): | Class IIa, Rule 9, MDD 93/42/EEC |

Applied standards and normative standards:

US: ANSI 63.19-2006
MDD: IEC 60118-0:83+A1:94, IEC 60118-7:2005, IEC 60118-13:2004, ISO 10993-5:2009, ISO 10993-10:2010, ISO 14971:2007
R&TTE: EN/(IEC) 60601-1-1:2001, EN/(IEC) 62311:2008 (Health & Safety)
EN/(IEC) 60601-1-2:2001+A1, EN/(IEC) 301 489-17 2.1.1:2009 (EMC)
EN/(IEC) 300 440-2 V1.3.1:2009 (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, 25 May 2011


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