EC Declaration of Conformity

Name	Version	Device Destination	Basic UDI-DI
Audiolyser® ADL20	✓ Holmco PD-81 (FF1077) ✓ Sennheiser HDA300 (FF1001)	Computerized audiometer destinated to the exploration/screening of auditive function	**376025345FF1001SX**

Medical devices conform to the following standards:

NF EN ISO 13485 :2016 : Medical Device – Quality Management System
NF ISO 2859-1 :2000 : Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
EN 60601-1:2006/A1:2013: Medical electrical equipment – Part 1: General requirements for basic safety
EN 60601-1-2:2015: Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2007/AC: 2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015: Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5:2009: Biological evaluation of medical devices - Partie 5 : Tests for in vitro cytotoxicity
EN ISO 10993-10:2010: Biological evaluation of medical devices - Partie 10 : Tests for irritation and skin sensitization
NF EN ISO 14971:2019: Medical devices - Application of risk management to medical devices
NF EN 62304/A1:2018 : Medical device software -- Software life cycle processes
NF EN 1041 + A1: 2013: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
IEC 60645-1: 2012 : Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone audiometry
ISO 8253-1: 2010 Acoustics - Audiometric test methods - Part 1: audiometry with pure air conduction and bone conduction sound.
ISO 389-1: 2000 Acoustics - Reference zero for the calibration of audiometric equipment - Part 1: Levels Reference equivalent threshold sound pressure earphones at supra-aural pure sounds
ISO 389-8: 2004 Acoustics - Reference zero for the calibration of audiometric equipment - Part 1: Levels Reference equivalent threshold sound pressure for pure tones and circumaural headphones
NF EN ISO 7029: 2017 Acoustics-statistical distribution of hearing thresholds as a function of age

I the undersigned, Dounia Benbachir, Quality Manager the FIM MEDICAL company located at 51 rue Antoine Primat Villeurbanne - FRANCE assure and declare that the medical devices listed above belong to class IIa (Rule 10) and satisfy the provisions of annex I (Essential Requirements), annex VI (Product Quality Assurance) and annex VII (Evaluation of Audiolyser® ADL20 FF1001DTR100 technical file) of the 93/42/EEC directive and its local adaptation (Book V of the public health code).
The devices described above are covered by the EC Certificate n° 27671 delivered by LNE/G-MED, 1 rue Gaston Boissier, 75724 Paris Cedex 15.

Villeurbanne, 09/07/2021,
D.BENBACHIR

Responsable Qualité

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