UE 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/Amd 1:2020: Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2020: 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
ISO 10993-10:2021: 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
ISO 20417:2021: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
IEC 60645-1: 2012 & 2017: 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 of 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) satisfy the requirements of Medical Device Regulation 2017/745 under annex IX chapter I & III and section 4 for technical file evaluation assessment (13485 QMS Certificate N'38723 rev.0 issued by GMED and technical file ADL20 FF1001DTR100) and all of the annexes (except annexes VII, X, XI, XII, XIII, XV, et XVI) and all others Union legislative acts applicable to the devices listed above.

Villeurbanne, 15/06/2022
D.BENBACHIR
Responsable Qualité

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