EC Declaration of Conformity

Name	Device Destination	Basic UDI-DI
Earpad covers (SS1101)	Accessories Hygienic biocompatible single-use earpad covers for audiometric headphones Audiolyser® ADL20	**376025345FF1075TU**

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 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 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

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 I (Rule 1) and satisfy the provisions of annex I (Essential Requirements), and annex VII (Evaluation of Audiolyseur® ADL20, FF1001DTR100 technical file) of the 93/42/EEC directive and its local adaptation (Book V of the public health code).

A Villeurbanne, le 09/07/2021,
D.BENBACHIR

Responsable Qualité

CE