CE Declaration of conformity

Manufacturer :

Électronique du Mazet
ZA Route de Tence
43520 Le Mazet St Voy

Unique registration number: APP000005035

Device(s) concerned by this declaration:

Designation of the device (destination)	Internal technical file reference (product code)	Commercial reference (name and trade name)	Basic IUD-ID
Active medical device for otological diagnosis	**ECH001**	**ELIOS** ECH001KP110	137013302ECH001KP1XXKH
		BABYSCREEN ECH001KP120	
		EchoScan ECH001KP130	
		AudioSmart ECH001KP140	
		AudioSchool ECH001KP150	
		OtoWin ECH001KP160	

Class of the device according to Annex 9 of Directive 93/42/EEC: class IIa rule 10
Class of the device according to Annex VIII of the EU Regulation 2017/745: class IIa rule 10

Date of first placing on the market: October 2019

Applicable regulatory texts, directives, laws and decrees:

- Quality assurance system in accordance with Annex II excluding point 4 of the Medical Devices Directive 93/42/EEC. (Amendment 2007/47/EEC)
  - Decree 95-292 of application in French law of the European directive 93/42/CEE
  - Decree n°2009-482 of April 28, 2009 implementing the European Directive 2007/47/EEC in French law
- RoHS III Directive 2017/2102/EU (amendment 2017/2102 & 2015/863/EU)
  - Decree n°2019-1431 of December 23rd, 2019 implementing the European Directive 2015/863/EU in French law
  - Decree n°2019-1431 of December 23rd, 2019 on the limitation of the use of certain hazardous substances in electrical and electronic equipment
- Reach Regulation n° 1907/2006
- DEEE Directive 2012/19/EU
  - Decree n° 2014-928 of August 19, 2014 implementing in French law the European Directive 2012/19/EU
- RTTE Directive 99/5/EC
  - Decree 2003-961 of October 8, 2003 implementing in French law the European Directive 1999/5/EC
  - EU Regulation 2017/745

Notified Body :
The LNE/G-MED notified body n°0459 located at 1, rue Gaston Boissier 75724 Paris cedex15 attests in its certificate **n°33287 rev.4 of December 8, 2020** and in its annex that the quality assurance system for the quality and final inspection of the medical devices listed above complies with the requirements of Annex II excluding point 4 of Directive 93/42/EEC.
Électronique du Mazet assures and declares that the products named above comply with the provisions of the applicable directives listed above and their transposition(s) into local law.

Declaration of Conformity established
At: Le Mazet St Voy **On**: March 19, 2021

Sébastien AILLERET
Président