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Date: 2023.06.11 15:46:58 EEST
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COMPLIANCE & STANDARDS

PRO35 F

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CE

EC DECLARATION OF CONFORMITY
Of REGULATION EU 2017/745

This declaration has been released under the exclusive responsibility of PUMA s.r.l. in quality of manufacturer of the product.

PUMA s.r.l., based in via Alessandro Volta 17, Settimo Milanese (MI),
declares that the soundproof booth
for audiometric tests or similar
PRO 35F Model
GMDN (Global Medical Device Nomenclature) n° 37020
CND: (National Classification (Italy) of Medical Devices) n° Z12149002
PRODUCT REGISTRATION NUMBER:7872
Ministry of Health registration n°2227561
Base UDI-DI 805750785P35FZ12149002XX
Labeled with the serial number
Pxxxxxxxxx#.

It is classified as a medical device Class, I annex VIII, as non-invasive medical device.
Paragraph 4, chapter 4.1 and complies with regulation EU 2017/745
concerning medical devices.

Furthermore, it declares that the soundproof booth complies with:
CEI 64/11 'electrical systems in furniture "
CEI 64-8 (710-751) "electrical installations"
2014/35/EU "Low Voltage Directive for devices and equipment".
2014/30/EU "Electromagnetic compatibility".
2011/65/EU and ss.mm.ii "restriction of the use of certain hazardous substances in electrical and electronic equipment"
EN ISO 717-1 140-4 "Airborne sound insulation assessment"
EN ISO 717-1 11957 "Evaluation of airborne sound insulation in place"
UNI EN ISO 8253-1 and subsequent "Audiometric test methods".

Settimo Milanese - MILANO
25/03/2023

Technical manager
Fabrizio Museli

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European Regulation EU 2017/745 for MEDICAL DEVICES CLASS I
Soundproof booths for audiometric test in compliance with EU 2017/745
concerning non-invasive *Class I Medical Devices.*

The undersigned company, **puma s.r.l**., a company incorporated under the Italian laws, with registered seat located at 17, Via Volta, 20019 Settimo Milanese, Milano, Italy, enrolled in Milano Chamber of Commerce under no. 1346141, with Fiscal Code and VAT number 10114440158, in person of its legal representative, Mr. Mauro Muselli, duly empowered to sign off the present, hereby declares that the company afterwards set forth:

Device(s) category

Soundproof booths for audiometric testing
Cabins in *Class I Medical Devices* without measurement function

Soundproof booths (manufacturer: puma) for audiometric test are conform with **European Regulation EU 2017/745** regarding non-invasive *Class I Medical Devices*.
There are not parts directly in contact with the patient. The booths can be used only for audiometric examinations or similar and not for other medical purposes with components applied to the patient where is necessary to have different specifications. The manufacturer (puma) is responsible for ensuring that his product complies with all the relevant Essential Requirements of the Directive and must draw up a written statement to this effect (self-declaration). *Class I Medical Device* without a measuring function and supplied in non-sterile condition does NOT require the involvement of a Notified Body. Conformity to the International and European Standard EN ISO 13485 is voluntary.

ISO 13485
ISO 13485 norm for Medical Device is part of the ISO 9001 norm, used for design, manufacture and marketing of overall medical devices. ISO 13845 is important when the products are sterile/barren and invasive/intrusive, and for safety reasons must be traceable and should be stored according to specifications.
Medical devices are classified according European Regulation EU 2017/745 for the use from non-invasive (Class I) to invasive (sterile/barren) (Class II and Class III).
Is not required ISO certification for Puma company as manufacturer of non-invasive Class I Medical Devices

Conformity Declaration Medical Devices EU 2017/745
Puma company as manufacturer emits a **Conformity Declaration Medical Devices EU 2017/745** conform with standards: CEI 64/11, CEI 64/8, 2014/35/EU, 2014/30/EU, EN ISO 717-1 140-4, EN ISO 717-1 11957, UNI EN ISO 8253-1:2010 and subsequent.
For commercialization and use it is not required additional declaration.

CE marking
Soundproof booths are classified as *Class I Medical Devices* without measurement function following EU 2017/745 Annex VIII.

Products registration for silent cabins at the Italian Ministry of Health

Puma is registered at the Italian Ministry of Health as a manufacturer of silent cabins *Class I Medical Devices*, according with **Medical Devices EU 2017/745** conform with standards, CEI 64/11, CEI 64/8, 2014/35/EU, 2014/30/EU, EN ISO 717-1 140-4, EN ISO 717-1 11957, UNI EN ISO 8253-1:2010 and subsequent. Puma has **Conformity Declaration EU 2017/745** for all commercialized models of soundproof booth for whom the Italian Ministry of Health has issued a registration number.

