



DECLARATION OF CONFORMITY

Audiometric Booth

Annex 7B



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 30 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° 2227100

SRN (Single Registration Number) IT-MF-000029419

Base UDI-DI 805750785P30Z12149002UY

Labeled with the serial number

Pxxxxxxxxxx#.

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 "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

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