

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 25 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° 2227172#
Base UDI-DI 805750785P25Z12149002YJ
Labeled with the serial number

Pxxxxxxx

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 "Audiometric test methods".

Settimo Milanese - MILANO
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