

**Annex 7B****EC DECLARATION OF CONFORMITY
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 28F Model

GMDN (Global Medical Device Nomenclature) n° 37020

CND: (National Classification (Italy) of Medical Devices) n° Z12149002

MANUFACTURER CODE:7872

Ministry of Health registration n°2224551#

SRN (Single Registration Number) IT-MF-000029419

BASE UDI-DI 805750785P28FZ12149002ZP

UDI-DI xxxxxxxxxxxxxxxxx

Labeled with the serial number

Pxxxxxxxxxxxxxxxxxx

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

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