

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  
**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 "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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