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CE

COMPLIANCE E NORMATIVE

PRO25 - PRO25 *slim*

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DICHIARAZIONE DI CONFORMITA' CE
MDD 93/42/CEE - 2007/47/CE - CEI 64/11- CEI 64/8 - 2006/95/CE

La PUMA s.r.l. fabbricante del prodotto in oggetto
dichiara che la cabina silente

Modello: **PRO 25**
GMDN:37020
CND:Z12149002
CODICE FABBRICANTE:7872
Registrazione Ministero di Sanità n° 705087#

Etichettata con il numero di serie
P00000000#.

E' classificata come dispositivo medico di CLASSE I ed è conforme alla direttiva 93/42 CEE armonizzata con la 2007/47/CE concernente i dispositivi medici.

Inoltre dichiara che la cabina silente è conforme a:

CEI 64/11 "impianti elettrici nei mobili"
CEI 64-8 (710-751) "impianti elettrici utilizzatori"
2006/95/CE "Direttiva bassa tensione per dispositivi e macchinari".
2004/108/CE "Compatibilità elettromagnetica".
UNI EN ISO 8253-1 " metodi di prova audiometrici".

6 luglio 2017

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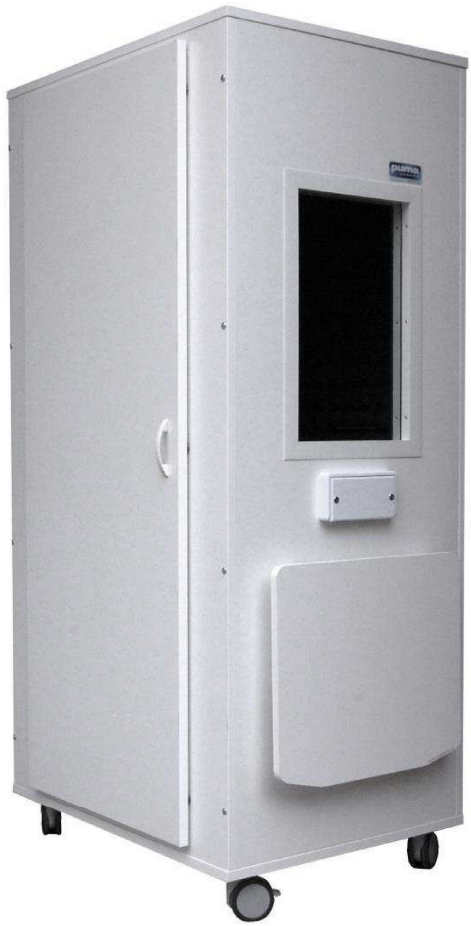
CE

COMPLIANCE & STANDARDS

PRO25 - PRO25 *slim*



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EC DECLARATION OF CONFORMITY
MDD 93/42/EEC - 2007/47/EC - CEI 64/11 - CEI 64/8
2006/95/EC

PUMA s.r.l. manufacturer of the product in the present document,
declares that the soundproof booth

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° 705087#

Labeled with the serial number
P00000000#.

It is classified as a medical device Class I and complies with EEC Directive 93/42 harmonized with the 2007/7/EC 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"
Directive 2006/95/EC "Low Voltage Directive for devices and equipment".
2004/108/CE "Electromagnetic compatibility".
UNI EN ISO 8253-1 "Audiometric test methods".

July 6, 2017

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PRO 25 013 rev 07 compliance e standards Puma s.r.l. 2017 all right reserved

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DIRECTIVE 93/42/CEE for MEDICAL DEVICES CLASS I
Soundproof booths for audiometric test conform with directive 93/42/CEE
regarding non-invasive *Class I Medical Devices* harmonized with directive 2007/47/CE.

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 **Medical Devices Directive MDD 93/42/CEE** regarding non-invasive *Class I Medical Devices* harmonized with directive 2007/47/CE. There are not parts directly attached to 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 to Directive 93/42/CEE 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 Directive MDD 93/42/CEE
Puma company as manufacturer emits a **Conformity Declaration Medical Devices Directive MDD 93/42/CEE** conform with standards: 2007/47/CE, CEI 64/11, CEI 64/8, 2006/95/CE, EN ISO 717-1 140-4, EN ISO 717-1 11957, UNI EN ISO 8253-1:2010.
For commercialization and use is not required additional declaration.

CE marking
Soundproof booths are classified as *Class I Medical Devices* without measurement function following CEE 93/42 Annex IX and have CE marking following CEE 93/42 Annex VII.

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 Directive MDD 93/42/CEE** conform with standards: 2007/47/CE, CEI 64/11 CEI 64/8, 2006/95/CE, EN ISO 717-1 140-4, EN ISO 717-1 11957, UNI EN ISO 8253-1:2010. Puma has **Conformity Declaration MDD 93/42/CEE** for all commercialized models of soundproof booth for whom the Italian Ministry of Health has issued a registration number.

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