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DECLARATION ABOUT REQUIRED ISO 13485:2016 ON PUMA S.R.L. AUDIOMETRIC BOOTHS

Puma S.r.l. manufactures soundproof booths for audiometric testing classified according to EC directive 93/42 harmonized with 2007/47 / EC.
Starting from the end of May 2021 the new European regulation 2017/745 came into force repealing the previous directives; Puma has adopted the official documentation to the new provisions.

From a clinical evaluation (attached to all the booths in production) it is clear that there is no interaction between the booth and the patient, furthermore, the object does not emit any substances and does not provide measurement data;

Considering the above listed reasons there is no need to certify the compliance with the general requirements of safety and performance since the results related to the audiometric booth's technical properties (which exclusively relate to soundproofing, acoustic and fire-reaction) have been released following NON-clinical testing methods.

Our silent booths are classified as class I medical devices according to Annex VIII of EU regulation 2017/745 CND code Z12149002.

These are the main reasons why ISO 13485: 2016 certification is not currently mandatory.

Moreover, due to the above listed reasons, it is not allowed to request the CE marking from an external certification institute. The CE marking must be performed internally by self-declaration.

The audiometric booths have a conform electrical system which allows to connect electro-medical devices and it can be installed in medical environments classified as GROUP 1 and in ordinary rooms.

Yours faithfully,

Fabrizio Muselli,
Technical Director

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