



CE Conformity Assessment

(Directive 93/42/EEC, Directive 47/2007/EC concerning Medical devices/ Annex VII)

MEDICAL DEVICE MADE IN SERIES OF CLASS I

Mr. David Verde Sánchez

in name and representation of the company Think Pipe Line, S.L.U.

established in Calle Cintaires, 9-bajos - 08243 MANRESA (BARCELONA) – SPAIN

DECLARES: that the medical device COJIN MIMOS and its accessories PILLOWCASE MIMOS fulfill the essential applicable requirements established in the Annex I of the Directive, and therefor the absence of compromise for the health and safety of people is guaranteed, always considering the product being used for its allowed purpose, and also the fulfilling of the assigned performance qualities.

COMPROMISES: To establish and maintain an actualized systematic procedure, in order to revise the experience acquired with the products in the after production phase, using the opportune means to apply the necessary corrective means. In the same way,



COMPROMISES: To inform the competent authorities about the following facts as soon as knowing them:

a/ Any malfunction or alteration of the characteristics or performance qualities, or any inadequate propriety of the label or the using instructions of a product that may cause death or severe alteration of the patient's or user's health;

b/ Any technical or sanitary reason bounded to the characteristics or performance qualities of a product because of the reasons of the preceding paragraph that have induced the producer to retire the products of the same type of the market.

Date: 1st of March 2017

Signed:



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