



Telic, S.A.U.

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Bigues, January 15th, 2019

SUBJECT: Market withdrawal and stop commercialization for the product Blayco® Disposable Electrode Tip Cleaner REF AL-40

DATE: 15/01/2019

Dear Sirs,

By middle of the past year, the possibility of changing the production process of the product Blayco® Disposable Electrode Tip Cleaner REF AL-40 was evaluated, affecting the packaging and sterilization process of the product.

As shown by the validation reports of the packaging and sterilization process, this modification does not affect compliance with the essential requirements, risk analysis or the intended use of the product.

According with the recommendation of the NB-MED/2.5.2/Rec2 “Reporting of design changes and changes of the quality system”, TELIC considered that the change was not substantial.

In accordance with this consideration, TELIC, S.A.U. started to commercialized the product after the relevant validations were finished and information was submitted to the Notified Body. After the evaluation of the sent documents, the Notified Body considered that implemented change was significant and required prior approval for the commercialization of the product.

For this reason, TELIC, S.A.U. has proceeded to withdraw the product from the market and stop the commercialization of the product Blayco® Disposable Electrode Tip Cleaner REF AL-40 until obtaining the documental approval of the change from our Notified Body.

In the next hours, TELIC, S.A.U. will contact you to coordinate the best solution and the withdrawal of all possible units of the batch 101/08-18 still available in the market.

We remain at your disposal for any questions or doubts you may have.

Sincerely,

Oscar Lacruz
CEO
TELIC, S.A.U.