

Brescia, 24 November 2020

STABILITY TEMPERATURE DECLARATION

TO WHOM IT MAY CONCERN

We, Copan Italia S.p.A., hereby declare that product code FLOQSwabs[®] 516CS01 should be stored at 2°C to 30°C as stated on labeling and must not be freezed.

Product performance is guaranteed within the above-mentioned label temperature range for the entire shelf life of the product (36 months).

In addition, we declare that, in order to evaluate the stability out of storage temperatures, Copan laboratory performed studies whose data confirmed that this product performs as intended after exposure up to 6 weeks at temperatures of 39 °C.

Sincerely,

Elisabetta Zanella Chief Regulatory Officer COPAN ITALIA S.p.A

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