

# DECLARATION OF CONFORMITY

## Chemical Strip Indicator for Steam “Sterigut” Code: 105229

**LOT : 05329**

 : **05-2023**

 : **05-2028**

We, PERGUT MEDICAL SLU – Isla de la Palma, 32 Nave 4, 28703 San Sebastián de los Reyes, Madrid -Spain- declare that:

- The Chemical Indicators for Steam are produced conforms with EN 867-4 and the ISO 11140-1 of Sterilization of healthcare product: Chemical indicators.
- The internal chemical indicators are made according to the section 4.4 classification like MULTIPARAMETERS INDICATORS TYPE 4.
- All the provided chemical indicators are based on system of change to a final stable color (End point), that once achieve does not have effect of possible reversion of color.
- The Indicators do not release any toxic substance enough that may cause health hazard, either before, during or after the sterilization process for which it was designed.
- The Indicators are not sanitary products, consequently the CE stamp is not compulsory.
- The stability of the final color after the sterilization process is guaranteed by a minimum of 5 years.

Made in Madrid, August 29th, 2023

  
**PERGUT MEDICAL, S.L.U**  
Isla de Palma, 32 Nave 4  
28703 San Sebastián de los Reyes  
Madrid (Spain)

Alfredo Lafuente  
General Manager

## DECLARATION OF NON TOXICITY

We, PERGUT MEDICAL SLU – Isla de la Palma, 32 Nave 4, 28703 San Sebastián de los Reyes, Madrid -Spain- declare that our products classified in the following range:

### **Chemical Strip Indicator for Steam “Sterigut” Code: 105229**

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Are produced in conformity with the requirements of applicable International and European Standards: EN-ISO 11140-1 of January of 2.005 Sterilization of healthcare product: Chemical indicators. Part 1 General requirements. Chapter 10 – additional requirements for MULTIVARIABLE (Type 4) Indicators

The Indicators do not release any toxic substance enough that may cause health hazard, either before, during or after the sterilization process for which it was designed.

Migration tests through the front and back of the indicators cycles have been made in sterilization cycles in accordance with AAMI standards for BIER (Biological Integrator Resistometer Evaluator) to 121 ° and 134 ° C.

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