

## DECLARATION OF CONFORMITY

Informer Med. Ltd hereby declares that:

- **STERIM Biological Indicator for VH202 Plasma Sterilization (product code PBI-050)** is manufactured accordingly to ISO 11138-1:2017 "Sterilization of health care products- Biological Indicators – Part 1: General requirements" and ISO 18472:2009 "Sterilization of health care products- Biological and chemical indicators- Test equipment".
- STERIM Biological Indicator for VH202 Plasma Sterilization contains spores of *Geobacillus stearothermophilus* 10<sup>6</sup> and provides a full visual biological result after 24 hours of incubation at 55-60°C. The vials fit to incubators of different manufacturers. Once the color in the vial changes to yellow it means bacterial growth has started. The PBI-050 BI's are intended for monitoring Vaporized Hydrogen Peroxide Sterilization Processes.
- STERIM Biological Indicator for VH202 Plasma Sterilization meets the performance requirements for use in the STERRAD® , V-PRO®, RENOSEM® sterilization cycles.

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