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maxill u·test Instant Release BI Plus™

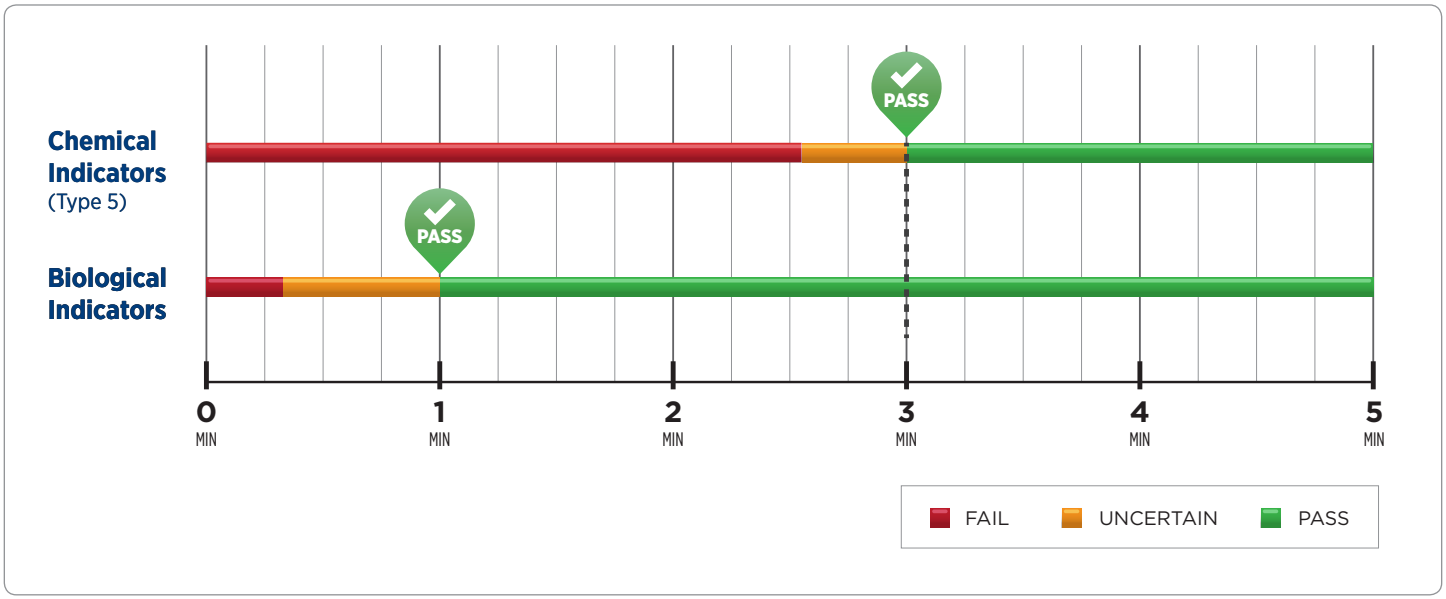
The Instant Release BI Plus™ features a built in Type (Class) 5 chemical indicator (CI). This allows the results to be instantly evaluated at the end of the sterilization process, eliminating the need to wait 24 hours for the outcome of the SCBI incubation. The load can be released with total confidence if the Type 5 indicator shows a pass upon completion of sterilization. The results from the SCBI provide a secondary verification and satisfy regulatory requirements.



How does the Instant Release BI Plus allow for instant evaluation of the sterilization cycle?

The Instant Release BI Plus has been tested and validated to prove that the CI requires more exposure to change from FAIL to PASS than the BI. The Type 5 indicator takes more than twice the time to change the indicator colour (resulting in a PASS) in comparison to the required 1-minute kill time for the BI (see graph). Therefore, the CI is more sensitive to insufficient sterilization conditions and is superior in function when compared to a BI. If the CI shows a pass, the BI test is a 100% pass.

Indicator Type	Standard	Fail Time	Pass Time	Temperature
Chemical Indicator (Type 5)	EN ISO 11140-1	2.55 minutes	3 minutes	135°C
Biological Indicator	EN ISO 11138-1 + 3	0.33 minutes	1 minute	134°C



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Testing Details:
All testing was completed by SAL-GmbH a DAkkS accredited laboratory. All procedures used, follow the directives 93/42/EWG, 90/386/EWG and DIN-EN-ISO/IEC 17025 for conduction microbiological hygienic and physical tests on biological and chemical indicators for sterilization monitoring.

Equivalence test of chemical and biological indicator:
The chemical and biological indicators were exposed to saturated steam for 1 min, 2 min and 3 min at 134°C. Twenty samples were used for each test. The results demonstrate clearly that the chemical indicator requires more exposure to change from FAIL to PASS than the biological indicator. Thus, the chemical indicator is more sensitive to insufficient sterilization conditions and the function of the chemical indicator as a prediction tool for the biological indicator was confirmed.

When the chemical indicator turns black, the test is a 100% pass. You may choose to incubate for 24 h to satisfy other protocols, but the test will pass if the chemical indicator shows a passed upon completion of the sterilization.

Test details for BI validation:
Population value, the number of colony forming units (CFU) in each SCBI.

The stated population values on the product Certificate of Analysis (CoA) was verified.

The spore discs were homogenised then diluted with sterile distilled water to approximately 30 to 300 CFU/mL

The USP heat shock process was followed, half of the culture was heat shocked and the other remained intact. The colonies were then plated and incubated for two days at 55-60°C.

The final counts were then compared to the certificates provided. The measured population was determined to be above the product claim across all three lots tested.

D-value is the time under specified conditions, required to kill 90% of a population.

Twenty samples were checked with the resistometer, according to EN ISO 18472 by survivor curve method according to DIN EN ISO 11138 at 121°C. The values were then compared to the CoA.

The certificate claims did not deviate from all three lots tested.

z-value is the number of degrees the temperature must increase in order to cause a ten-fold reduction in the D-value.

Sixty samples were tested in accordance to EN ISO 11183-3, determined at 118°C, 121°C and 124°C

The measured z-values were found to be within the measurement inaccuracy of the claimed temperatures of the certificate, thus they meet the standard.

Test of incubation time, comparing results at 24 h and 7 days to show consistency in results.

The stated incubation time of 24 h at 55-60°C was tested with one hundred samples with a sterilization cycle partially damaging the BI.

The SCBIs must show the same results after 24 h as after 7 days of prolonged incubation.

The Instant BI Plus SCBI showed consistent results with all Three lots tested, therefore a 24 h incubation time is valid.

Packing and design, must meet requirements set by EN ISO 11138 for biological indicator DFU.

The three lots tested all conform with the standard.