

CERTIFICATE

BAG-EaZy Test

This is to confirm that the self-contained biological indicators BAG-EaZy Test STEAM (REF 7482, 7483) and BAG-EaZy Test EO (REF 7484) are manufactured in compliance with ISO 11138. The following ATCC-listed strains are used:

- ATCC 7953 *Geobacillus stearothermophilus*
- ATCC 9372 *Bacillus atrophaeus*

BAG-EaZy Test self-contained biological indicators are manufactured according to “**United States Pharmacopeia (USP 26)**” and “**Food and Drug Administration Good Manufacturing Practises (FDACGMP)**”.

The manufacturing site and procedures are surveyed by the US authority “**Food and Drug Administration (FDA)**”. US-FDA Registration No. is **1921058**. There were no objections.

Read-out time has been validated for 24 hours for BAG-EaZy Test STEAM and for 48 hours for BAG-EaZy Test EO in accordance with FDA guidance on Validation of Reduced Incubation for Biological indicators.

Data for population, D-values, Z-values and expiry date are indicated for each lot and certificates are delivered to the end user.

BAG Health Care GmbH

August 2007



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