

## Declaration of Conformity

### T-EZ Pro® Cleaning Indicator

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#### EN ISO 15883-5: Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy

#### ANSI/AMAMI ST79 & ST90

The T-EZ Pro test soil is a true blood test soil and correlates to coagulated blood described in EN ISO 15883-5. T-EZ Pro utilizes defibrinated sheep's blood with a mixture of polysaccharides, and other ingredients to simulate the composition of human coagulated blood.

The T-EZ Pro cleaning indicators are standardized and used for monitoring the cleaning efficacy when reprocessing surgical instruments in automated washers. Blood is the main contaminant of surgical instruments and it is used as a test soil to check the efficacy of cleaning procedures per EN ISO 15883. Using a true blood standardized test soil that is consistently manufactured in an ISO 13485 environment provides a cleaning verification indicator that is an accurate representation of the most common contamination found in healthcare and provides for an indicator that is consistent in formulation and reproducible. The true blood test soil is placed onto a stainless-steel coupon and covered by a challenge device representing the hard to clean portion of surgical instruments. The T-EZ Pro is designed with a clear window for easy visual inspection for blood residue and can be used for evaluation of the test result. The T-EZ Pro unique design allows the user to remove the stainless-steel coupon and, if desired, perform additional quantitative tests.

#### The conformity relates to the following test methods:

##### EN ISO 15883 describes two test methods:

1. Quarterly routine test: EN ISO 15883-1 / 6.10.2 Cleaning efficacy test - A test load is contaminated with one of the test soils (Annex A) and inspected for residues after the cleaning process.
2. Daily routine test: EN ISO 15883-1 / 6.10.3 Cleaning efficacy test - An actual load contaminated by normal use is cleaned and visually inspected for residues. In addition, a chemical method for protein/blood detection can be used.

The T-EZ Pro contains a correlating true blood test soil while the challenge device simulates a hard to clean surgical instrument in a test load to satisfy testing according to the methods mentioned above. The T-EZ Pro Cleaning Indicator allows for easy visual inspection and can help detect physical, chemical, and mechanical cleaning problems that may occur.



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