



**TOSI®**

## **Declaration of conformity to cleaning efficacy Tests (EN ISO 15883-1 / 15883-5)**

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The TOSI® test soil correlates to coagulated blood described in EN ISO 15883-5. Standardisation and correlation is achieved by the use of purified and standardised bovine protein fractions. A two-component system including the coagulation factors fibrinogen and thrombin is used to achieve coagulation as in human blood or reactivated animal blood. The coagulation factors are embedded in a matrix of purified albumin and haemoglobin simulating the composition of blood.

The TOSI® cleaning indicators are standardised cleaning indicators 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 per EN ISO 15883 as a test soil to check the efficacy of cleaning procedures. Since the composition of blood varies, reproducibility is a critical factor. Using a standardised test soil correlating to the properties of coagulated human blood has overcome this problem. The standardised test soil is dosed onto test objects representing the joint of surgical instruments and are designed for easy visual evaluation. To simulate other types of instruments additional test objects like LumCheck or FlexiCheck are used. Visual inspection or chemical tests for blood residue can be used for evaluation of the test result.

### **Conformity of test methods**

EN ISO 15883 describes two test methods:

#### **A) Quarterly routine test: EN ISO 15883-1 / 6.10.2 Cleaning efficacy test - 1**

A test load is contaminated with one of the test soils (Annex A) and inspected for residues after the cleaning process.

TOSI® is manufactured according to this test method using a correlating and standardised test soil while the test objects simulate the test load. The special design of the TOSI® cleaning indicator allows for an easy and more effective visual inspection compared to the inspection of the real instruments: While TOSI® can easily detect chemical cleaning problems by showing fibrin residue however, fibrin cannot be detected inside joints of surgical instruments with the described methods in the standards (visual detection, swabbing or SDS elution). The TOSI® is also designed to indicate mechanical cleaning problems by showing red haemoglobin residue.

#### **B) Daily routine test: EN ISO 15883-1 / 6.10.3 Cleaning efficacy test - 2**

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 TOSI® test objects simulate standard surgical instruments as described above. The TOSI® test soil correlates to human blood, the most common type of soil found in practice. Visual inspection for residues is used for evaluation of the results however, chemical methods for detection of blood residues can be used in addition (e.g.: HemoCheck-S).

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