

KPRO2-E69

Hygiene Monitoring System.

Kit system for detecting residual protein on surfaces.



Usage

Designed to detect proteins on surfaces of surgical equipment after the cleaning process and in hard to reach areas.

Applicable Regulation

ISO15883-1 / HTM2030 / HTM 01-05

Product Classification

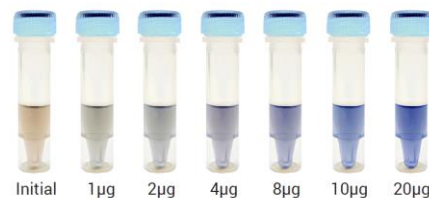
Class 1, according to risk.

Authorization

Designed under Quality Management System standard ISO 9001:2008.

Characteristics

- The system has a high absorption 6.9 cm long swab, SW69, as well as a reactive colorimetric solution. The SW69 swab allows the collection of samples from different surfaces with the same efficacy following the cleaning process.
- Volume of solution: 0.440 ml.
- An instant and visual reading of a color change indicates the presence of detectable levels of protein. By comparing the color of the test against the table an estimation of the surface cleanliness can be made.
- KPRO2-E69 can detect as little as 1 µg of protein.



Environmental conditions during manufacture

15-30 °C (room temperature), RH 30-80 %.

Storage conditions

T = 2-25 °C, RH 35-60 %, store in dark place.

Transportation conditions

Storage conditions should be strictly followed.

Transport in closed and strengthened boxes in order to avoid damages. Transportation of this product does not represent a risk for health.

Shelf-life

24 months when stored refrigerated (2°C – 8 °C) and 6 months when stored at room temperature up to 25 °C.

Packing

50 units per box + 50 SW69 swabs + 2 moisturizer tubes for swabs.
Packing information: product code and description, process for intended use, classification according to regulation, manufacturer information and data on label.

Labelling

On product's box: Product code and description, batch number and expiration date.

Possible target markets

Healthcare, Food, Pharmaceutical and Medical industries.

Other important information (optional)

Read product's directions for use thoroughly before use.

Note: When necessary, limits for each product's parameters should be specified.

Description of identified and/or predictable risks which could represent a risk for the product

Do not open until its use.

Do not reuse.

Do not touch the swab with your hands. Wear gloves, surgical mask and other hygiene measures.

Do not freeze.

Although PRO2 has high sensitivity, it is not a microbiological monitoring device, and surfaces may not be considered to be sterile based on the results obtained.