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INFORMATION SHEET

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SUBJECT	CLEANLINESS OF CUSTOMIZED PRODUCTS	SHEET #	PROPRETE.FIE

UNIMED (contract manufacturer) delivers customized product to its customers (legal manufacturer).

A customized product can be a component of a medical device, even a complete medical device but without its final packaging.

UNIMED WASHING VS. FINAL CLEANING

UNIMED guarantees to delivery customized products free from manufacturing residues. This means that no dirt is visible to the unaided eye and that their manipulation can be done without fouling. So this is a cosmetic washing.

The UNIMED washing is performed with a controlled, repeatable and reproducible process in a normal environment without control of dust or other micro-contaminants. It can not therefore be considered a qualified final cleaning for a medical device.

A qualified final cleaning must guarantee an appropriate definitive cleanliness of a medical device prior to packaging, even its sterilization. The final cleaning is the responsibility of the customer and it should be performed in a controlled environment.

BIOLOGICAL PROPRIETIES

The guarantee of the biological proprieties (biocompatibility) of a medical device is required per the essential requirements of the European directive of medical device 93/42/CEE and FDA requirements. This guarantee must be provided by the legal manufacturer of the medical device.

UNIMED being a contract manufacturer of customized products for a legal manufacturer, it is impossible to ensure the final biological proprieties of delivered customized products.

The standard ISO 10993-1 and the FDA guidance *"Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* allow a legal manufacturer to determine the biological evaluation of a medical device in 3 distinct steps.

1. Analyse of materials composing the medical device.
2. Evaluation of the risk of a biological contamination based on use and composition elements of the medical device.
3. Necessary biological trial(s) of medical device.

The guarantee of the biological proprieties of a medical device by its legal manufacturer must take into account different elements during development and realization of the technical file (or equivalent) of the medical device.

The following list (non-exhaustive) is to take into account to determine and evaluate the biological proprieties of a medical device:

- Use and performance of the medical device
- Materials composing the medical device
- Manufacturing and assembling processes of the medical device
- Final cleaning of the medical device
- Packaging of the medical device
- Sterilization of the medical device

UNIMED is ready to accompany you in the realization of samples and tests, and a definition of an appropriate washing to your needs according to our resources.