HOW COPAN ADJUSTED TO THE NEW INTERNATIONAL STANDARD ISO 18385:2016 IN ORDER TO MINIMIZE THE RISKS OF DETECTABLE HUMAN DNA CONTAMINATION IN ITS FORENSIC PRODUCTS

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The International Standard ISO 18385:2016, published in February 2016, specifies the requirements needed for the products with forensic DNA purposes. In order to minimize the risk of human DNA contamination during the manufacturing process, the ISO 18385 Standard requires a policy for staff contamination detection system and a quality system in action. Manufacturers have to perform a risk evaluation for potential human contamination, implement environmental monitoring procedures, a post-production treatment and release each lot of products that is not post-production treated.

Copan human DNA free (hDNA free) devices dedicated to forensic applications are: 4N6FLOQSwabs®, NAO®basket, microFLOQ® and NUCLEIC-CARD™.

Copan declared full compliance with the ISO by performing the following activities:

- Quality Controls on Raw Materials (on every raw material coming from suppliers, in order to exclude its contamination of amplifiable human DNA);
- Risk Assessment of the Manufacturing Process to identify potential causes of hDNA contamination;
- Dedicated staff for forensic products (gowning procedures are established and specific training is performed);
- Staff elimination database: Since 2012, Copan maintains a STR database of all the people involved in the manufacturing of the forensic products (including the ones involved in maintenance, cleaning and QC controls). More than 300 STR profiles are collected, and can be shared with customers (specific procedures are followed to guarantee privacy and informed consent of the donors). STR profiles are obtained from buccal swabs (optional, but mandatory if entering hDNA free areas);
- Automated manufacturing and restricted areas (hDNA free areas with access controls);
- Environmental Control (performed periodically on hDNA free areas);
- Ethylene oxide (EO) treatment validation: a treatment using ethylene oxide is applied on forensic products in order to reduce the risk of DNA contamination. This treatment is validated to demonstrate the required DNA reduction-factor of 1000, and not to leave EO residual after treatment, which could affect subsequent DNA analysis;
- Final Quality Control Testing: even if EO is applied, a qualitative detection approach (STR profiling) is adopted when testing the samples of finished product for every lot released: a kit containing 16 relevant STR markers is used, and the acceptance criteria follow the ISO.

Copan has therefore adjusted its guidelines to be consistent with the ISO 18385:2016 and to avoid hDNA contamination during the production of forensic items.