ISO 18385 Forensic DNA Grade Certificate

Our commitment to quality

The ISO 18385:2016 “Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes – requirements“ applies to the manufacturing of consumables for forensic DNA purposes including DNA extraction kits. The ultimate aim is to minimize the risk of human DNA contamination in forensic workflows.

MACHEREY-NAGEL has committed to these standards for quality by implementing all requirements of this international standard. In addition we also meet, where feasible, the guidelines of the European Network of Forensic Science Institutes (ENFSI), the Scientific Working Group on DNA Analysis Methods (SWGDAM*) and the Biology Specialist Advisory Group (BSAG). Key elements of the manufacturing comprise:

- Production of forensic products:
  Production processes designed to minimize the risks of human DNA contaminations. High degree of automation and dedicated, strictly controlled work environments including positive air pressure for critical manufacturing processes. Strict adherence to cleaning procedures, SOPs and extensive training of staff.

- Staff elimination database:
  For exclusion of contamination, MN maintains a staff elimination database containing DNA profiles of all employees involved in the production of forensic products.

- Forensic quality management system:
  For highest forensic quality, standards are continuously updated by a dedicated MN Forensic team. Corrective and preventive actions guarantee the highest forensic standards.

- Post production:
  All consumables used in our forensic product line are treated (post-production) with ethylene oxide (EO), to guarantee the absence of detectable human DNA. Validated batch-release testing includes tests for the absence of human DNA according to ISO 18385 Annex A.

By product labeling with the “ISO 18385 Certified forensic quality“ logo, MACHEREY-NAGEL declares the ISO 18385:2016 compliant manufacturing of these products.

*SWGDAM Contamination Prevention and Detection Guidelines for Forensic DNA Laboratories, 01/12/2017

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