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STATEMENT OF FACT

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Re: SceneSafe Evidence Recovery Systems

Adherence to ISO 18385:2016 “Minimising the Risk of Human DNA Contamination in Products Used to Collect, Store and Analyse Biological Material for Forensic Purposes”
and the

Forensic Regulators Guidance Manual FSR-G-206 Issue 1 “The Control and Avoidance of Contamination in Crime Scene Examination Involving DNA Evidence Recovery”

With the increasing sensitivity of amplification systems used in forensics, even a small amount of contamination may corrupt or confuse the DNA analysis process. It is now even more important that those involved in forensic science can be assured that the consumable equipment they are using has a traceable and validated background, enabling them to use it with confidence. ISO 18385:2016 and FSR-G-206 have been created to provide a road map for manufacturers and suppliers to minimise the risk of occurrence of detectable DNA contamination in products used in forensic analysis.

Both the ISO 18385 Standard and FSR-G-206 Guidance require manufacturers and suppliers to have a wide ranging quality system in place. This system should as a minimum perform risk assessments to identify weak points in the supply chain where potential human contamination could occur, have a policy for a searchable staff DNA database, have an environmental monitoring procedure policy in place, include post-production treatment using certificated DNA denaturing techniques for products where such a treatment does not negatively impact product performance and only release validated products once batch testing has been completed. Underpinning this standard should be the use of accredited ISO 17025 analytical service providers, BS 6002 accredited quality sampling processes and ISO 14644 accredited controlled manufacturing environments.

Only when all of the above is in place, along with the ability to robustly demonstrate their adherence to this standard, can suppliers be able to label specific consumables as an “ISO 18385 Forensic DNA Grade Product”. SceneSafe, together with other manufacturers, was directly involved in the draft review of the ISO 18385 from its beginning. With our technical expertise, combined experience and worldwide reputation, SceneSafe have developed and stock a full range of products to support the continued advances in Forensic Science. SceneSafe are at the forefront of forensic development taking technology to new levels.

SceneSafe Evidence Recovery Systems confirms it fully meets the above requirements of ISO 18385 and adheres to guidance as set out in FSR-G-206.

All SceneSafe ISO 18385 Forensic DNA Grade products are assessed in accordance with the following criterion:

Robust Quality Management System	<ul style="list-style-type: none"> • SceneSafe are ISO 9001:2015 Quality and ISO 14001:2015 Environmental Certified. We are fully committed to maintaining our UKAS accreditations to ensure we meet our customer and regulatory obligations. Copies of our ISO standards are available upon request. • Full AQL testing in accordance with BS 6002 testing guidelines and utilising measured quantities of DNA provided and validated by independent ISO 17025 accredited analytical service providers. • Each batch is accredited / certificated along with control samples of each batch held. • Adherence to internal procedures applicable to forensic products such as ISO 18385 and FSR-G-206
Mitigation of Potential Risk of Human DNA Contamination	<ul style="list-style-type: none"> • Kits are manufactured in restricted controlled environments (SceneSafe have their own on-site ISO 14644 Class 5 clean rooms which are environmentally monitored for DNA and GSR contamination) • Assembled by staff whose DNA profiles are held on the National Manufacturers Elimination Database (This database also extends to any regular contractor who visits our site. The profiles are anonymously held and searchable by the analytical service providers and law enforcement community) • Specialist clean room technicians fully trained in DNA preventative contamination risk avoidance (including gowning procedures and specialist cleaning of kit preparation areas).
Post Production Treatment (where applicable)	<ul style="list-style-type: none"> • SceneSafe use Ethylene Oxide Gassing (EtO) as a post-production technique and can demonstrate that the treatment is effective at reducing amplifiable human DNA by a reduction factor of at least 1000 in accordance with ISO 18385 Annex A3 (Compliance Testing). With internal procedures to further reduce the risk of DNA contamination on those products where the process is possible. • For those products that cannot be EtO treated, further Acceptance Quality Limits (AQL's) are utilised on each batch in accordance with BS 6002 testing guidelines. • Both of the above processes are validated by independent ISO 17025 accredited analytical service providers.

About SceneSafe

Originally part of the UK Home Office Forensic Science Service (FSS), SceneSafe was acquired by the WA Group in 2013. With a reputation for quality, innovation and service, SceneSafe is a worldwide leading supplier of evidence collection consumables, kits and equipment for use by the forensics / law enforcement community. For more information, visit www.scenesafe.co.uk or contact us at sales@scenesafe.co.uk

For SceneSafe™ (Part of the WA Group)



Mike Hopson
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