SQA-iO Test Kit- Safety Date Sheet

(P/N: IO-CA-01680-00, IO-CA-01783-00)

The SQA-iO Test Kit manufactured by Medical Electronic Systems (MES) is composed of several components:

1. Plastic capillaries and cleaning paddles (which are exempt from SDS requirements- please see the section “Exemption from SDS requirements” below on this page, page 1)
2. QwikCheck Test Strips (please see the SDS of the product below- pages 2-4)
3. Cleaning solution (please see the SDS of the product below- pages 5-8)

Exemption from SDS requirements:

Products that are manufactured or fabricated into an “article” typically are whole units that do not and cannot pose a risk in that they cannot be ingested, inhaled, or absorbed into the body through the skin, eyes, or mucous membranes under normal conditions of use. As such, these products are exempt from the SDS requirements.

According to 29 CFR 1910.1200 (c), the Occupational Safety and Health Administration (OSHA) defines an article as”... a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end-use function(s) dependent in whole or in part upon its shape or design during end-use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

The SQA-iO Test Kit manufactured by Medical Electronic Systems (MES) is considered to be an “article” as specified by the Hazard Communication Standard and is therefore exempt from the requirements of the Standard according to the Occupational Safety and Health Administration (OSHA).

Revision date: 14 AUG 2025
Reviewed and approved by: Taly Vider, Regulatory Affairs and IP Director

QwikCheck Test Strips- SAFETY DATA SHEET

Section 1: Identification	
Product identifier	QwikCheck Test Strips
Product number	A-CA-01681-00, A-CA-02219-00, A-CA-02216-00, A-CA-02218-00
Manufacturer/ Representative	**Manufacturer:** MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL
Recommended use	QwikCheck™ Test Strips are for in vitro diagnostic use for the determination of pH and leukocytes (WBCs) in semen. The test is semi-quantitative.
Section 2: Hazard Identification	
Classification of the substance or mixture	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This product is not classified as dangerous according to Directive 67/548/EEC.
Label elements	The product does not need to be labeled in accordance with EC directives or respective national laws.
Other hazards	None
Section 3: Composition/Information on Ingredients	
Mixtures	Buffered salts, enzymes, pH indicators on plastic strips. Other components either non-hazardous or at concentrations below that requiring hazardous listing

Section 4: First-Aid Measures

Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration.
Eyes: Flush eyes with water as a precaution.
Skin: Wash with soap and water after each contact.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed:
The most important known symptoms and effects are described in the labeling (see Section 2) and/or in section 11.

Section 5: Fire-Fighting Measures

Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance or mixture: carbon oxides, hydrogen bromide gas.
Advice for firefighters: Wear self contained breathing apparatus for fire-fighting if necessary.
Further information: No data available.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Pick up. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for safe handling: Normal measures for preventive fire protection. For precautions see section 2.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place. Stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20^{0}C to +37^{0}C.

Section 8: Exposure Controls/Personal Protection

Exposure controls: General industrial hygiene practice.

Personal protective equipment:
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Respiratory protection is not required.
Control of environmental exposure: Do not let product enter drains.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

- Appearance Form: solid
- Odor/Odor Threshold: no data available
- pH: no data available
- Melting point/freezing point: no data available
- Initial boiling point and boiling range: no data available
- Flash point: no data available
- Evaporation rate: no data available
- Flammability (solid, gas): no data available
- Upper/lower flammability or explosive limits: no data available
- Vapor pressure/density: no data available
- Relative density: no data available
- Water solubility: no data available
- Partition coefficient: n-octanol/water: no data available
- Auto-ignition temperature: no data available
- Decomposition temperature: no data available
- Viscosity: no data available
- Explosive properties: no data available
- Oxidizing properties: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: no data available
Incompatible materials: strong oxidizing agents
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity: no data available
Skin corrosion/irritation: no data available
Serious eye damage/eye irritation: no data available
Respiratory or skin sensitisation: no data available
Germ cell mutagenicity: no data available
Carcinogenicity IARC: No component of this product present at levels ≥ 0.1% is identified as a probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity: no data available
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional Information: RTECS: LM5800000
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Ecological information

Persistence and degradability: no data available
Bioaccumulation: not determined
Aquatic toxicity: no data available
Ecotoxicity effects: no data available
Mobility in soil: no data available
Results of PBT and vPvB assessment: no data available

Other adverse effects: no data available

Section 13: Disposal considerations

Waste from residues / unused products:
Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous

Section 14: Transport information

UN number:
- ADR/RID: -
- IMDG: -
- IATA: -

UN proper shipping name
- ADR/RID: Not dangerous goods
- IMDG: Not dangerous goods
- IATA: Not dangerous goods

Transport hazard class(es)
- ADR/RID: -
- IMDG: -
- IATA: -

Packaging group
- ADR/RID: -
- IMDG: -
- IATA: -

Environmental hazards
- ADR/RID: no
- IMDG Marine pollutant: no
- IATA: no

Special precautions for user: no data available

Section 15: Regulatory information

This product complies with regulations:

CE: IVDD 98\79\EC / IVDR (EU) 2017/746
FDA: # K063864
Health Canada: # 95821

Complies with Regulation (EC) No. 1907/2006 (REACH), Annex II, and subsequent amendments introduced by Commission Regulation (EU) No. 2020/878

Australian sponsor: Acrapack PTY LTD
Emergency Phone: +61 7 56410159 / +61 7 54490087
www.acrapack.com.au

Section 16: Additional Comments

NA

SQA-iO cleaning solution- SAFETY DATA SHEET

Section 1: Identification	
Product identifier	SQA-iO cleaning solution
Product number	A-CA-01684-00, A-CA-02219-00, A-CA-02216-00, A-CA-02218-00
Manufacturer/ Representative	**Manufacturer:** MES Medical Electronic Systems, Ltd 20 Alon Hatavor Street Zone 6 Caesarea Industrial Park 3088900 ISRAEL
Recommended use	The cleaning solution is intended for both routine and contamination cleaning of the labeled devices.
Section 2: Hazard(s) Identification	
Classification of the substance or mixture	**Classification according to Regulation (EC) No 1272/2008** Flammable liquids (Category 2), H225 **Classification according to EU Directives 67/548/EEC or 1999/45/EC** F, Highly flammable, R11
Label elements	**Labeling according Regulation (EC) No 1272/2008**  Pictogram Signal word: Danger **Hazard statement(s)** H225: Highly flammable liquid and vapor. **Precautionary statement(s)** P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Supplemental Hazard Statements: none
Other hazards	None
Section 3: Composition/Information of Ingredients	
Mixtures	• Ethanol (CAS No.64-17-5) - 50% • Tween 20 (CAS No.9005-64-5) - 0.5%
Section 4: First-Aid Measures	
General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. **Inhalation:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician. **Eyes**: Rinse thoroughly with a copious amount of water for at least 15 minutes and consult a physician. **Skin**: Wash off with soap and a copious amount of water. Consult a physician. **Ingestion**: Do NOT induce vomiting. Rinse mouth with water – only if the person is conscious. Consult a physician. **Most important symptoms and effects, both acute and delayed**: Refer to the labeling (see Section 2 and/or section 11).	
Section 5: Fire-Fighting Measures	
Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. **Special hazards arising from the substance or mixture:** No data available. **Advice for firefighters:** Wear self contained breathing apparatus for fire-fighting if necessary. **Further information**: Use water spray to cool unopened containers.	

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations.

Section 7: Handling and Storage

Precautions for safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep away from sources of ignition - No smoking. Take measures to prevent the build-up of electrostatic charge. For precautions see section 2.
Conditions for safe storage, including any incompatibilities: Store at room temperature. Keep containers tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Exposure controls
General industrial hygiene practice.

Personal protective equipment
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: Do not let product enter drains.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties
a) Appearance Form: liquid, clear, colorless
b) Odor: no data available
c) Odor Threshold: no data available
d) pH: no data available
e) Melting point/freezing point: no data available
f) Initial boiling point and boiling range: no data available
g) Flash point: no data available
h) Evaporation rate: no data available
i) Flammability (solid, gas): no data available
j) Upper/lower flammability or explosive limits: no data available
k) Vapor pressure: no data available
l) Vapor density: no data available
m) Relative density: no data available
n) Water solubility: no data available
o) Partition coefficient: n-octanol/water: no data available
p) Auto-ignition temperature: no data available
q) Decomposition temperature: no data available
r) Viscosity: no data available
s) Explosive properties: no data available
t) Oxidizing properties: no data available

Other safety information: no data available

Section 10: Stability and Reactivity

Reactivity: no data available
Chemical stability: stable under recommended storage conditions.
Possibility of hazardous reactions: no data available
Conditions to avoid: Heat, flames and sparks. Extremes of temperature and direct sunlight.
Incompatible materials: Alkali metals, Oxidizing agents, Peroxides
Hazardous decomposition products: no data available
Other decomposition products: no data available
In the event of fire: see Section 5

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity LD50
Oral - Rat - 7.060 mg/kg
Remarks: Lungs, Thorax, or Respiration: Other changes.
LC50 Inhalation - Rat - 10 h - 20000 ppm
Skin corrosion/irritation
Skin - Rabbit
Result: No skin irritation - 24 h
(OECD Test Guideline 404)
Serious eye damage/eye irritation
Eyes - Rabbit
Result: Mild eye irritation - 24 h
(OECD Test Guideline 405)
Respiratory or skin sensitization: No data available
Germ cell mutagenicity: No data available
Carcinogenicity
Carcinogenicity - Mouse - Oral
Tumorigenic: Equivocal tumorigenic agent by RTECS criteria.
Liver: Tumors. Blood: Lymphomas including Hodgkin's disease.
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity
Reproductive toxicity - Human - female - Oral Effects on Newborn: Apgar score (human only).
Effects on Newborn: Other neonatal measures or effects.
Effects on Newborn: Drug dependence.
Specific target organ toxicity - single exposure: No data available
Specific target organ toxicity - repeated exposure: No data available
Aspiration hazard: No data available
Additional Information RTECS: KQ6300000
Central nervous system depression, narcosis, Damage to the heart.
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section 12: Ecological information

The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Persistence and degradability: no data available
Bioaccumulation: not determined
Aquatic toxicity: no data available
Ecotoxicity effects: no data available
Mobility in soil: no data available
Results of PBT and vPvB assessment: no data available

Other adverse effects: no data available

Section 13: Disposal considerations

Waste treatment methods
Product: Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging: Dispose of as unused product.

Section 14: Transport information

UN number:
- ADR/RID: 1170
- IMDG: 1170
- IATA: 1170

UN proper shipping name
- ADR/RID: ETHANOL
- IMDG: ETHANOL
- IATA: ETHANOL

Transport hazard class(es)
- ADR/RID: 3
- IMDG: 3
- IATA: 3

Packaging group
- ADR/RID: II
- IMDG: II
- IATA: II

Environmental hazards
- ADR/RID: no
- IMDG Marine pollutant: no
- IATA: no

Special precautions for user: no data available

*****This product is an exception as it is packed in small quantities (30ml) and combined packaging. No transport limitations should be applied to it.**

Section 15: Regulatory

This product complies with regulations:

CE: IVDD 98\79\EC, IVDR (EU) 2017/746
FDA: NA - NON MEDICAL DEVICE
Health Canada: NA - NON MEDICAL DEVICE

Complies with Regulation (EC) No. 1907/2006 (REACH), Annex II, and subsequent amendments introduced by Commission Regulation (EU) No. 2020/878

Australian sponsor: Acrapack PTY LTD
Emergency Phone: +61 7 56410159 / +61 7 54490087
www.acrapack.com.au

Section 16: Additional Information

Full text of H-Statements referred to under sections 2 and 3.
H225: Highly flammable liquid and vapor
H225: Highly flammable liquid and vapor

Full text of R-Statements referred to under sections 2 and 3.
R11: Highly flammable

Full text of P-Statements referred to under sections 2 and 3.
P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking

All information presented above is correct to the best of our knowledge and Medical Electronic Systems does not claim that the information is all-inclusive but recommends that it should be used as a guide. Medical Electronic Systems shall not be held liable for any damage resulting from handling or from contact with the product.