



ATTN: Importer / Customs / Health Canada Inspector,

Attached to this document are the Health Canada approval statements for the Medical Electronic Systems (MES) product line. Below is a list of all relevant MES items with product numbers and descriptions for reference. For any specific questions on the approval or release of these items please contact Medical Electronic Systems at 310-670-9066 or sales@mes-llc.com.

Medical Electronic Systems Product List

Item Code	Item Description
VS-FA-01147-00	SQA-VISION™ Automated Sperm Quality Analyzer System - Including PC Quantity: 1 Unit of Measure: Each Ships in: 5~10 Business Days
V-FA-00740-00	SQA-V Gold™ Automated Sperm Quality Analyzer System - Including PC Quantity: 1 Unit of Measure: Each Ships in: 5~10 Business Days
4021	Testing Capillaries for SQA-V and SQA-VISION Quantity: 50 Unit of Measure: Box Ships in: 1~2 Business Days
0115	Cleaning Kit for SQA-V and SQA-VISION Quantity: 25 Unit of Measure: Kit Ships in: 1~2 Business Days
0200	QwikCheck™ Quality Control Beads Quantity: 3 Unit of Measure: 5ml Vials (1 level each) Ships in: 1~2 Business Days
0700	QwikCheck™ WBC/pH Test Strips Quantity: 100 Unit of Measure: Bottle Ships in: 1~2 Business Days
0800	QwikCheck™ Dilution Kit Quantity: 1 Unit of Measure: 50ml Bottle Ships in: 1~2 Business Days
0900	QwikCheck™ Liquefaction Kit Quantity: 25 Unit of Measure: 10µl Vials Ships in: 1~2 Business Days
A-CA-01057-00	QwikCheck™ Vitality Kit Quantity: 5 Unit of Measure: 1.5ml Vials Ships in: 1~2 Business Days
A-CA-01082-00	QwikCheck™ Fixed Cover Slip Slides Kit Quantity: 24 Unit of Measure: Double Sided Slides Ships in: 1~2 Business Days
A-CA-00691-00	Validation Kit for SQA Systems (Accuracy, Precision, Linearity) Quantity: 1 Unit of Measure: Kit Ships in 1~2 Business Days



Licence Number **6658** Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

MES MEDICAL ELECTRONIC SYSTEMS LTD.

ALON HATAVOR 20, ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA
ISRAEL
0038900

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made :

Attestations faites :

<p>The establishment has documented procedures in place in respect of:</p> <ul style="list-style-type: none"> distribution records complaint handling recalls mandatory problem reporting handling, storage, delivery installation corrective action servicing 	<p>[Y]</p> <p>[Y]</p> <p>[Y]</p> <p>[N]</p> <p>[N]</p> <p>[N]</p> <p>[N]</p> <p>[N]</p>	<p>L'établissement a mis en oeuvre une procédure écrite concernant:</p> <ul style="list-style-type: none"> les registres de distribution les plaintes les rappels rapports d'incident obligatoires la manutention, le stockage, la livraison l'installation, les mesures correctives l'entretien
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Site listing begins on the back of this page

Liste des sites commence au verso de cette page

Issue Date, date de délivrance: 2015-05-22

<p>Minister of Health / Ministre de la santé</p>	<p>Countersigned: Director General, Health Products & Food Branch Inspectorate or delegated authority Contresigné par: Directeur Général, Inspectorat de la Direction générale des produits de santé et des aliments ou autorité déléguée</p> <p> Etienne Ouimette</p>
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This licence is the property of the Health Products & Food Branch Inspectorate and must be returned upon demand. Cette licence appartient au programme d'Inspectorat de la Direction générale des produits de santé et des aliments et doit être retournée sur demande.

Sites

MES MEDICAL ELECTRONIC SYSTEMS LTD.
ALON HATAVOR 20, ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA
ISRAEL
0038900

Company ID

116608

No. d'identification
de la société



Medical Device Licence

Homologation d'un instrument médical

Licence Number:

95277

No d'homologation:

First Issue Date:

2015/06/05

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

SQA-V SPERM QUALITY ANALYZER

Licence Type/Type d'homologation:

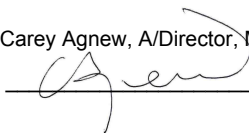
System / Système

Manufacturer Name & Address/Nom du fabricant & adresse

MES MEDICAL ELECTRONIC SYSTEMS LTD.

ALON HATAVOR 20, ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA
ISRAEL
0038900

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux



Application Number: 238716
Numéro de la demande:

Manufacturer ID: 116608
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

SQA-V GOLD SPERM QUALITY ANALYZER

Device ID/No de l'instrument: 806753

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

AS-9081000

SQA-VISION AUTOMATED SPERM QUALITY ANALYZER

Device ID/No de l'instrument: 806754

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

VS-MA-00892-00

SQA-VISION FIXED COVER SLIP SLIDES

Device ID/No de l'instrument: 806755

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

A-CA-01082-00



Medical Device Licence

Homologation d'un instrument médical

Licence Number:

95278

No d'homologation:

First Issue Date:

2015/06/05

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

QWIKCHECK BEADS VALIDATION AND TRAINING KIT

Licence Type/Type d'homologation:

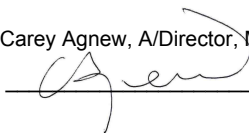
Test Kit / Trousse d'essai

Manufacturer Name & Address/Nom du fabricant & adresse

MES MEDICAL ELECTRONIC SYSTEMS LTD.

ALON HATAVOR 20, ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA
ISRAEL
0038900

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux



Application Number: 240223
Numéro de la demande:

Manufacturer ID: 116608
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

QWIKCHECK BEADS VALIDATION AND TRAINING KIT

Device ID/No de l'instrument: 806736

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

A-CA-00691-00



Medical Device Licence

Homologation d'un instrument médical

Licence Number:

95279

No d'homologation:

First Issue Date:

2015/06/05

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

QWIKCHECK BEADS

Licence Type/Type d'homologation:

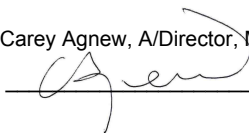
Test Kit / Trousse d'essai

Manufacturer Name & Address/Nom du fabricant & adresse

MES MEDICAL ELECTRONIC SYSTEMS LTD.

ALON HATAVOR 20, ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA
ISRAEL
0038900

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux



Application Number: 240224
Numéro de la demande:

Manufacturer ID: 116608
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

QWIKCHECK BEADS

Device ID/No de l'instrument: 806737

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

0200



Medical Device Licence

Homologation d'un instrument médical

Licence Number:

95280

No d'homologation:

First Issue Date:

2015/06/05

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

QWIKCHECK VITALITY

Licence Type/Type d'homologation:

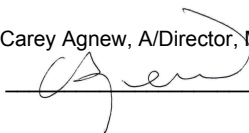
Test Kit / Trousse d'essai

Manufacturer Name & Address/Nom du fabricant & adresse

MES MEDICAL ELECTRONIC SYSTEMS LTD.

ALON HATAVOR 20, ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA
ISRAEL
0038900

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux



Application Number: 240225
Numéro de la demande:

Manufacturer ID: 116608
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

QWIKCHECK VITALITY

Device ID/No de l'instrument: 806738

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

A-CA-01057-00



Medical Device Licence

Homologation d'un instrument médical

Licence Number:

95281

No d'homologation:

First Issue Date:

2015/06/05

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

QWIKCHECK TEST STRIPS

Licence Type/Type d'homologation:

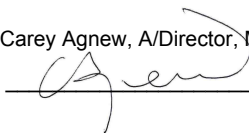
Test Kit / Trousse d'essai

Manufacturer Name & Address/Nom du fabricant & adresse

MES MEDICAL ELECTRONIC SYSTEMS LTD.

ALON HATAVOR 20, ZONE 6
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CAESAREA
ISRAEL
0038900

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux



Application Number: 240227
Numéro de la demande:

Manufacturer ID: 116608
Identificateur du fabricant:



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

QWIKCHECK TEST STRIPS

Device ID/No de l'instrument: 806739

**Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):**

0700

Therapeutic Products Directorate
Device Licensing Services Division
2934 Baseline Road, Tower B
Address Locator: 3403A
Ottawa, ON K1A 0K9

October 27, 2015

Mr. Taly Vider-Cohen
Regulatory, QA and Projects Manager
Medical Electronic Systems Ltd.

Dear Mr. Vider-Cohen,

This letter will serve as confirmation that the following products are either Class 1 medical devices or non-medical devices and as such, do not require a medical device licence as per the Medical Device Licence Regulations:

1. QuickCheck Liquefaction Kit: Class 1 medical device
2. QuickCheck Dilution Kit: Class 1 medical device
3. SQA Disposable Capillaries: not a medical device
4. SQA Capillary Compartment Cleaning Kit: not a medical device

I hope you will find this letter satisfactory.

Best regards,

Marie Rochefort
Medical Devices Bureau
Device Licensing Services Division