



## History of Regulatory Compliance for CleanTech® Automated Handwashing Stations

### CleanTech® meets handwashing requirements outlined by the FDA and USDA

CleanTech® Automated handwashing Stations meet hand hygiene requirements for food processing set by governmental agencies including the USDA and FDA. Based on two letters from the FDA as well as written guidelines for the Food Code, CleanTech® meets all FDA requirements for food service use. CleanTech® has also been reviewed by the USDA and was found to meet all FSIS requirements for use in meat and poultry processing. Detailed excerpts from the Food Code and letters from these governmental agencies can be found on the following pages:

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### CleanTech® has been reviewed by independent certifying agencies

Meritech's CleanTech® Automated Handwashing Stations have been reviewed by several independent certifying organizations like NSF, FCC and CSA. Each of these certifying bodies have found CleanTech® to meet food safety or medical electrical equipment standards. Certificates and product listings from NSF, a FCC letter and two CSA international certificates can be found on the following pages:

NSF International Certification.....	9
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#### Did you know?

Meritech used to be referred to as "Resugent Health and Medical", therefore you may see older letters in this packet that refer to the approval of CleanTech® Handwashing Stations addressed to that name. Letters from governmental agencies like the FDA and USDA never expire.

## Meritech hygiene solutions must be used to ensure efficacy

The performance and effectiveness of CleanTech® Automated Handwashing Stations have been extensively tested when using Meritech Hygiene Solutions. To learn more about the efficacy of CleanTech® stations, visit [www.meritech.com/efficacy](http://www.meritech.com/efficacy)

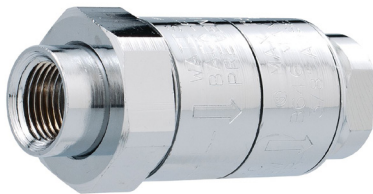
Satisfactory performance or effectiveness cannot be guaranteed when other solutions are used. **Failure to use Meritech Hygiene Solutions will void any and all warranties.** To order more Hygiene Solutions please email us at [info@meritech.com](mailto:info@meritech.com).

## If external backflow prevention is needed

If your local plumbing code requires, or additional backflow prevention is required external to the handwashing station, the following backflow preventers are suitable and approved for use with our systems. Two units will be required for each system, on each the hot and cold inlets.

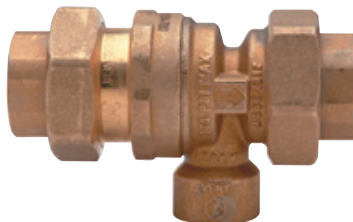
**Consult local and national codes: conformity and compliance to local and nation codes is the responsibility of the installer. Consult your local plumbing code for specific details for your location and use a certified plumber for proper installation.**

For ANSI / ASSE standard 1024 applications:



Watts® Series LF7

For ANSI / ASSE standard 1021 applications:



Zurn / Wilkens Model 760  
Part Number 12-760

For ANSI / ASSE standard 1056 applications:



Watts® Series  
LF008PCQT - 1/2"

## Contact our technical support team:



(800) 932-7707



[Service@Meritech.com](mailto:Service@Meritech.com)



[Meritech.com/support](http://Meritech.com/support)



# CleanTech® Meets FDA & USDA Requirements

Over the next few pages you'll see several documents detailing how CleanTech® Automated Handwashing Stations meet requirements for hand hygiene set by the United States Food & Drug Administration as well as the United States. These documents include quotes direction from the FDA Food Code detailing how automated handwashing stations like CleanTech® can be used, as well as two letters from the FDA detailing how there are no objections to the use of a CleanTech® station so long as food code requirements are met. A letter from the USDA is also included detailing how CleanTech® meets FSIS requirements.

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## 2017 FDA Food Code Sections Approving Use of CleanTech® Stations

Pursuant to the FDA Food Code, automated handwashing stations like CleanTech® are accepted for use in food establishments. The information provided in this section is quoted directly from the 2017 FDA Food Code:

### **Chapter 2: Management and Personnel**

#### Part 2-3: Personal Cleanliness

##### **Section 2-301.12: Hands and Arms; Cleaning Procedure.**

- (A) Except as specified in (D) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a HANDWASHING SINK that is equipped as specified under § 5-202.12 and Subpart 6-301.
- (D) If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, an automatic handwashing facility may be used by FOOD EMPLOYEES to clean their hands or surrogate prosthetic devices.

##### **Section 2-301.15: Hands and Arms; Where to Wash.**

FOOD EMPLOYEES shall clean their hands in a HANDWASHING SINK or APPROVED automatic handwashing facility and may not clean their hands in a sink used for FOOD preparation or WAREWASHING, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

## Chapter 5: Water, Plumbing, and Waste

### Part 5-2: Plumbing System

#### Section 5-202.12: Handwashing Sink, Installation.

- (A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet.
- (B) A steam mixing valve may not be used at a HANDWASHING SINK.
- (C) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- (D) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

#### Section 5-203.11: Numbers and Capacities, Handwashing Sinks.

- (A) Except as specified in (B) and (C) of this section, at least 1 HANDWASHING SINK, a number of HANDWASHING SINKS necessary for their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of HANDWASHING SINKS required by LAW shall be provided.
- (B) If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, automatic handwashing facilities may be substituted for HANDWASHING SINKS in a FOOD ESTABLISHMENT that has at least 1 HANDWASHING SINK.
- (C) If APPROVED, when FOOD exposure is limited and HANDWASHING SINKS are not conveniently available, such as in some mobile or TEMPORARY FOOD ESTABLISHMENTS or at some VENDING MACHINE LOCATIONS, EMPLOYEES may use chemically treated towelettes for handwashing.

#### Section 5-205.11: Operation and Maintenance, Using a Handwashing Sink.

- (A) A HANDWASHING SINK shall be maintained so that it is accessible at all times for EMPLOYEE use.
- (B) A HANDWASHING SINK may not be used for purposes other than handwashing.
- (C) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

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## 2011 Letter from the FDA Regarding the Use of CleanTech® Systems

The following is a letter from the FDA detailing how CleanTech® Handwashing Stations comply with the criteria outlined in the FDA's Food Codes and may be approved by state or local regulatory authorities as an alternative to manual handwashing procedures.





July 8, 2011

Jim Glenn, CEO  
Resurgent Health and Medical  
600 Corporate Circle  
Suite H  
Golden, Colorado 80401

**Re: Resurgent Health and Medical's CleanTech™ Automated Hand Cleansing System**

Dear Mr. Glenn:

The U.S. Food and Drug Administration (FDA) understands that automatic handwashing facilities, such as the CleanTech™ Automated Hand Cleansing System manufactured by Resurgent Health and Medical, are in use in many food establishments as part of a handwashing regimen. Food employees insert their soiled hands into these systems, which subject the hands to pressurized sprays of cleaning compounds. Section 2-301.12(D) of the 2009 FDA Food Code ("Food Code") recognizes that the use of an automatic handwashing facility by food establishments (as defined in section 1-201.10 of the Food Code) may be approved by state or local regulatory authorities as an alternative to the handwashing procedure described in section 2-301.12(B) of the Food Code, if the automatic handwashing facility is deemed capable of removing the types of soils that are encountered in the food operations involved. FDA understands that a number of State and local regulatory authorities have approved the use of automatic handwashing facilities in a number of food establishments in locations around the United States.

At least one State official has requested the opinion of FDA on whether a food establishment can comply with the Food Code if it uses the CleanTech™ Automated Hand Cleansing System when the system applies a 2% solution of chlorhexidine gluconate (CHG) as the cleaning compound. Section 2-301.16 of the Food Code addresses the acceptable food establishment uses of hand antiseptics, which are subject to regulation as drugs.

While the ultimate decision to accept or approve the use of any automatic handwashing facility in a food establishment rests with the regulatory authority that licenses or permits the establishment, at this time FDA does not object to the use of the CleanTech™ System with CHG for the purpose of general skin cleansing by employees in a food establishment, provided that all provisions of the Food Code relevant to its use are met, including that:

- the use of the automatic handwashing facility is approved by the regulatory authority (i.e., the permit issuing official), as required by section 2-301.12(D) of the Food Code;

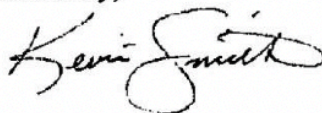
*Continued on the next page*

- the automatic handwashing facility is capable of removing the types of soils encountered in the food operations involved, as required by section 2-301.12(D) of the Food Code; and
- when used by any employee who may subsequently contact food with his or her hands, the application of the CHG solution is followed either by the use of gloves or by thorough hand rinsing in clean water. This is required by section 2-301.16(B) of the Food Code, due to the fact that the CHG solution does not meet the criteria specified under section 2-301.16(A)(2) of the Food Code.

The Food Code is available online at

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm>. The Food Code is not a regulation and serves as a model for regulations, codes and ordinances that are developed and enforced by State, local and tribal regulatory authorities that license and permit foodservice establishments and other retail food establishments under their jurisdiction. Food establishments are expected to comply with the prevailing statutes, regulations, codes and ordinances, which may or may not be the same as the Food Code with respect to the sections referred to in this letter.

Sincerely,



Kevin Smith

Director

Retail Food and Cooperative Programs Coordination Staff

Center for Food Safety and Applied Nutrition

Food and Drug Administration

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## 1999 Letter from FDA Regarding the Use of CleanTech® Systems

The following is a letter from the FDA to Meritech detailing how CleanTech® Handwashing Stations comply with the criteria outlined in the FDA's Food Codes and are deemed acceptable for handwashing in retail food establishments.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington DC 20204

29 October 1992

Mr. Don Berns  
Vice President, Operations  
MERITECH  
8250 South Akron Street, #202  
Englewood, Colorado 80112

Dear Mr. Berns:

This is in reply to your inquiry of October 6<sup>th</sup> and our telephone conversation of October 23<sup>rd</sup> concerning the CleanTech automated hand and glove cleansing systems (models 2000S, 2000 and 500). You indicated that an airline caterer has shown an interest in this product, and therefore, you requested approval of the product by the Food & Drug Administration (FDA).

FDA does not issue approvals relating to proprietary products. However, products used in retail food operations (restaurants, institutions, retail markets, or caterers) may be evaluated for acceptability based on provisions of the FDA model food protection codes or standards developed by third party equipment evaluation organizations.

The information you provided relating to the CleanTech Systems has been reviewed as was the article "Evaluation of Three Handwash Modalities Commonly Employed in the Food Processing Industry", published in Dairy, Food and Environmental Sanitation, September, 1992.

Based on this information, we find the CleanTech Systems to be consistent with the criteria of Section 3-201 of the model Food Service Sanitation Code as it relates to handwashing. Therefore, it is our opinion that the equipment is deemed acceptable for the purpose of handwashing in retail food establishments.

FDA's review of the CleanTech Systems and our finding that equipment complies with applicable criteria and provisions of model food protection codes does not constitute agency endorsement or approval. FDA does not have authority under the Food, Drug, and Cosmetic Act to approve specific products, and any representation on a label or in the literature that the product is "approved" by FDA would be false.

Please advise if further information is needed.

Sincerely,

Raymond D. Beaulieu  
Assistant Director  
for Codes & Practice  
Retail Food Protection Branch  
Center for Food Safety  
and Applied Nutrition

## 1992 Letter from the USDA Approving Use of CleanTech® Stations

The following is a letter from the United States Department of Agriculture Food Safety and Inspection Service approving the use of CleanTech® for meat and poultry plants.



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

March 24, 1992

Mr. Don Berns  
Meritech  
8250 South Akron Street #202  
Englewood, CO 80112

Dear Mr. Berns:

Thanks for your letter dated February 25, 1992, concerning the approval of your Hand Sanitizing Systems.

Mr. Berns, equipments such as your CleanTech Hand Sanitizing Systems, which has neither direct nor incidental contact with edible food product may be used in federally inspected meat and poultry plants without a formal letter of acceptance from this office provided:

1. They creates no adverse conditions or safety hazards.
3. They are installed, maintained, and operated in a manner acceptable to the inspector in charge.

If you have further questions concerning this matter please contact us.

Sincerely,

A handwritten signature in cursive script, appearing to read "Robert E. Owens".

Robert E. Owens

Industrial Specialist  
Equipment Branch  
Facilities, Equipment, and Sanitation Division  
Science and Technology



## CleanTech® has been reviewed by certifying agencies

Over the next few pages you'll see several documents detailing how CleanTech® Automated Handwashing Stations meet requirements for hand hygiene from organizations like NSF International, the FCC as well as CSA International.

### Certificate of approval from NSF International

The below document is a certification from NSF International recognizing Meritech as compliant with NSF/ANSI 169 regulations which establishes minimum food protection and sanitation requirements for the materials, design, fabrication, construction, and performance of special purpose food handling and processing equipment and devices not fully covered by other individual standards.



## Certificate of approval from CTO regarding FCC Rules

The below document is a letter from Paul Barnhill, Chief Technology Officer at Meritech detailing how CleanTech® Automated Handwashing Stations comply with part 15 of FCC rules.



From: Meritech Systems, LLC

Date: October 4, 2021

Re: FCC Compliance

Meritech manufactured Handwashing and Bootwashing stations/devices complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interferences that may cause undesired operation.

Should you need further clarification, please contact Paul Barnhill at the contact information listed below.

Paul R. Barnhill  
Meritech Systems, LLC  
720 Corporate Circle, Suite K  
Golden, CO 80401  
Phone: 303.790.4670 Ext. 118  
Fax: 303.790.4859  
Email: [pbarnhill@meritech.com](mailto:pbarnhill@meritech.com)

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## Certificates of Compliance from CSA International

Over the next few pages, you'll see documentation for two certificates of compliance for CleanTech® Automated Handwashing Stations from CSA International. These certificates verify that CleanTech® stations meet Class 8750 Medical Electrical Equipment standards in the United States.



# Certificate of Compliance

**Certificate:** 2039824

**Master Contract:** 237713

**Project:** 2039824

**Date Issued:** 2008/08/28

**Issued to:** Meritech Inc.

500 Corporate Circle  
Golden, CO 80401  
USA  
Attention: Paul Barnhill

*The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'*



**Issued by:** Dennis Smith

**Authorized by:** Patricia Pasemko, Operations Manager

## **PRODUCTS**

**CLASS 8750 81** - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

**CLASS 8750 01** - MEDICAL ELECTRICAL EQUIPMENT

Hand and glove cleansing system, Model IC/ELF, IC/ELF LCD, and IC/ELF LCD\_RFID, cord connected, stationary, rated: 100-250 Vac, 50/60 Hz, 3.2 A.

- Type of protection against electric shock: Class I
- Degree of protection against electric shock: No applied part
- Degree of protection against ingress of water: IPX0
- Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.





**Certificate:** 2039824

**Master Contract:** 237713

**Project:** 2039824

**Date Issued:** 2008/08/28

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nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

- Mode of operation: Continuous
- Environmental Conditions: Normal: 10-40°C, 30-75% rH, 700-1060hPa

### **APPLICABLE REQUIREMENTS**

CSA Standards:

CAN/CSA C22.2 601.1-M90

Medical Electrical Equipment part 1: General requirements for Safety adopted IEC 601-1 2ed (90)

CAN/CSA C22.2 601.1S1-94

Supplement No 1-94 to CAN/CSA C22.2 601.1-M90

CAN/CSA C22.2 601.1B-98

Amendment 2 to CAN/CSA C22.2 601.1-M90

UL Standards:

UL 60601-1 (1st edition)

Medical Electrical Equipment part 1: General requirements for Safety

### **MARKINGS**



# Certificate of Compliance

**Certificate:** 1866523

**Master Contract:** 237713

**Project:** 2203014

**Date Issued:** 2009/08/20

**Issued to:** Meritech Inc.

600 Corporate Circle, Suite H  
Golden, CO 80401  
USA  
Attention: Paul Barnhill

*The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only.*



*Dennis Smith*

Issued by: Dennis Smith

## **PRODUCTS**

**CLASS 8750 01** - MEDICAL ELECTRICAL EQUIPMENT

**CLASS 8750 81** - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

Hand and glove cleansing system Model 2000S, 400 and 500 EZ cord connected, stationary, rated: 100-250 Vac, 50-60 Hz, 3.2 A

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: No applied part
3. Degree of protection against ingress of water: IPX0
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous



**Certificate:** 1866523

**Master Contract:** 237713

**Project:** 2203014

**Date Issued:** 2009/08/20

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6. Environmental Conditions: Normal: 10-40°C, 30-75% rH, 700-1060hPa

**APPLICABLE REQUIREMENTS**

CSA Standards:

CAN/CSA C22.2 No. 601.1 M90 Medical Electrical Equipment Part I: General Requirements for Safety

CAN/CSA C22.2 No. 601.1S1 94 Supplement No. 1 94 to CAN/CSA C22.2 No. 601.1 M90

Medical Electrical Equipment Part 1: General Requirements for Safety

CAN/CSA C22.2 No. 601.1B-98 - Amendment 2 to CAN/CSA C22.2 No. 601.1 M90 Medical

Electrical Equipment-Part 1: General Requirement for Safety

UL Standards:

UL 60601-1 (1st edition) - Medical Electrical Equipment