



# CONAIR MEDLINE® EQUIPMENT

## CLEANROOM READY





## WHY MEDLINE?

Medline equipment fulfills two important needs for medical device manufacturers:

1. Easy implementation by the user into their highly regulated environment.

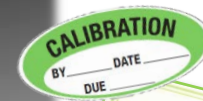
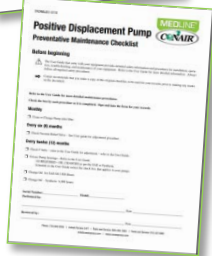
*Conair does most of the **certification homework** for medical processors!*

2. All MedLine equipment is **designed to meet compliancy specifications** for medical processing.





## WHY MEDLINE?



### Examples:

- Powder coated white paint, cleanroom complaint material components.
- Fully calibrated and traceable operating parameter testing.
- Sanitation considerations and exhaust minimization or elimination.





## Steps for applying MedLine equipment

### 1. Identify the equipment use location:

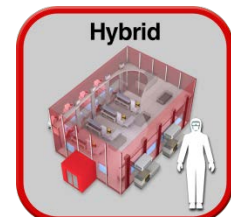
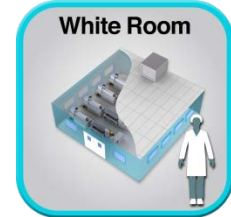
*This helps Conair clarify specifications.*

#### a. NON-CLEAN ROOM USE:

- For easy implementation into an existing manufacturing line for medical compliance.
- For inclusion in a future clean room.
- Otherwise, standard Conair equipment will suffice.

#### b. CLEAN ROOM USE: Four clean room types:

- White room:
- ISO 8 clean room
- ISO 7 clean room
- Hybrid clean room

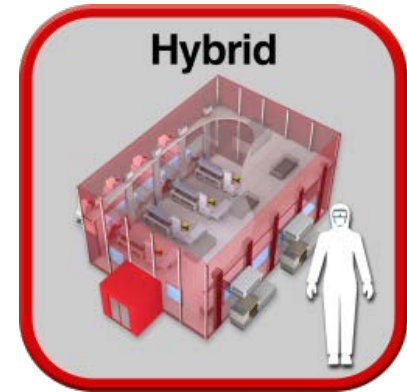
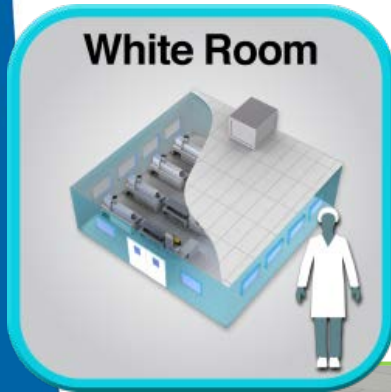






# Steps for applying MedLine equipment

## 1. Identify the equipment use location



*Different cleanliness levels drive different installation requirements.*





## Steps for applying MedLine equipment

### 2. Clarify MedLine compliancy:

*MedLine equipment provides compliance-ready specifications for easy implementation by medical manufacturers:*

- ISO International Standards Organization
- FDA Food and Drug Administration
- ICH International Conference on Harmonization Compliance
- CFR Code of Federal Regulations

*Conair provides a list of medical manufacturing compliancy codes with each MedLine equipment and system quote.*





## Steps for applying MedLine equipment

### 2. Clarify MedLine compliancy:

#### Some details:

- **Factory calibration**

Sensing devices critical to equipment operation are calibrated with certified measuring instruments to verify that the equipment provides optimum performance.

- **Calibration certificate**

A document, accompanied by a dated equipment sticker, verifies that calibration has been performed on required components to meet requirements that will assure the equipment functions at optimum performance.

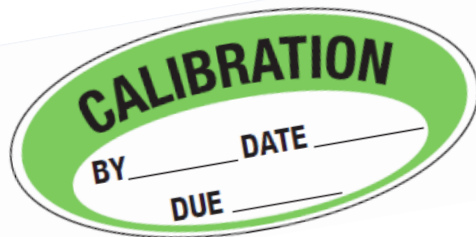
- **Calibration label**

A dated and initialed label, (accompanied by a signed and dated calibration certificate) that is affixed to the equipment that verifies that calibration has been performed on a specific month and year and provides the next calibration date interval requirement.



# Steps for applying MedLine equipment

## 2. Clarify MedLine compliancy:



Certificate of Calibration	
Product:	Model Number:
Serial Number:	Date:
<p>Specified Requirements: The MedLine Adiabatic cooler has been tested to the latest revision of Conair test procedures. The test verifies the RTD is functioning within acceptable parameters. Full operation of the unit for its intended use and function has been inspected and verified.</p> <p>Per the review and testing conducted by Conair and based upon the successfully completed fore mentioned test procedures, Conair confirms that this product conforms to the above specified requirements of Conair's quality and functionality standards. This calibration/certification should be performed annually from the date of this certificate. Please see owner's manual for calibration procedures</p>	
Authorized signature	For any further compliance information please contact Customer relations at: 814-437-6861 or service@conairgroup.com
The Conair MedLine logo, featuring the word "CONAIR" in a stylized font with a green and blue circular graphic element, and the word "MEDLINE" below it.	FM11.01b/XXXX





## Steps for applying MedLine equipment

### 2. Clarify MedLine compliancy:

- **ISO conformance documentation**

International Standards Organization conformance documentation. Control documents that are traceable and auditable with qualification signatures, dates and reviewed-by signatures in accordance with ISO 13485, CFR, cGMP (current Good Manufacturing Practices).

- **IQ checklist**

Installation Qualification checklist. A controlled document checklist that details installation requirements, verifies that each step is properly performed and that the equipment may be operated as intended.

- **PM checklist**

Preventative Maintenance checklist. A controlled document checklist that details the necessary equipment maintenance intervals for maintaining adequate calibration and audit compliancy.



# Steps for applying MedLine equipment

## 2. Clarify MedLine compliancy:

Installation  
Qualification  
(IQ) checklist

TPCPML001-0115

**MEDLINE<sup>™</sup>**  
**CONAIR**

### Positive Displacement Pump Installation Checklist

**Before beginning**

⚠ The User Guide that came with your equipment provides detailed safety information and procedures for installation, operation, troubleshooting, and maintenance of your equipment. Refer to the User Guide for more detailed information. Always follow all required safety procedures.

➡ Conair recommends that you make a copy of this original checklist, to be used for your records, prior to making any marks on the document.

After following the instructions contained in the Installation section of the Conair User Guide that came with the equipment, verify installation by the following Checklist:

- ☐ Set or mount the Vacuum Pump. \_\_\_\_\_ (fill in required voltage).
- ☐ Connect Power - Voltage \_\_\_\_\_
- ☐ Check Motor Rotation.
- ☐ Install the Vacuum Lines.
- ☐ Connect the Dust Collector Vacuum Outlet to the Pump Inlet.
- ☐ Connect the pump control to the material conveying system control pump output.

Serial Number: \_\_\_\_\_ Model: \_\_\_\_\_

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

Phone: 724.584.5500 | Instant Access 24/7 — Parts and Service: 800.458.1960 | Parts and Service: 814.437.6861  
info@conairgroup.com | www.conairgroup.com

TPCPML001-0115

**MEDLINE<sup>™</sup>**  
**CONAIR**

### Positive Displacement Pump Preventative Maintenance Checklist

**Before beginning**

⚠ The User Guide that came with your equipment provides detailed safety information and procedures for installation, operation, troubleshooting, and maintenance of your equipment. Refer to the User Guide for more detailed information. Always follow all required safety procedures.

➡ Conair recommends that you make a copy of this original checklist, to be used for your records, prior to making any marks on the document.

Refer to the User Guide for more detailed maintenance procedures.

Check the box by each procedure as it is completed. Sign and date the form for your records.

**Monthly**

- ☐ Clean or Change Pump inlet filter.

**Every six (6) months**

- ☐ Check Vacuum Relief Valve - See User guide for adjustment procedure.

**Every twelve (12) months**

- ☐ Check V belts - refer to the User Guide for adjustment - refer to the User Guide.
- ☐ Grease Pump bearings - Refer to the User Guide.  
AS REQUIRED - OIL CHANGES as per the SAE or Synthetic.  
Schedule in the User Guide (select the check box that applies to your pump).
- ☐ Change Oil for SAE Oil 1500 Hours.
- ☐ Change Oil - Synthetic 6,000 hours.

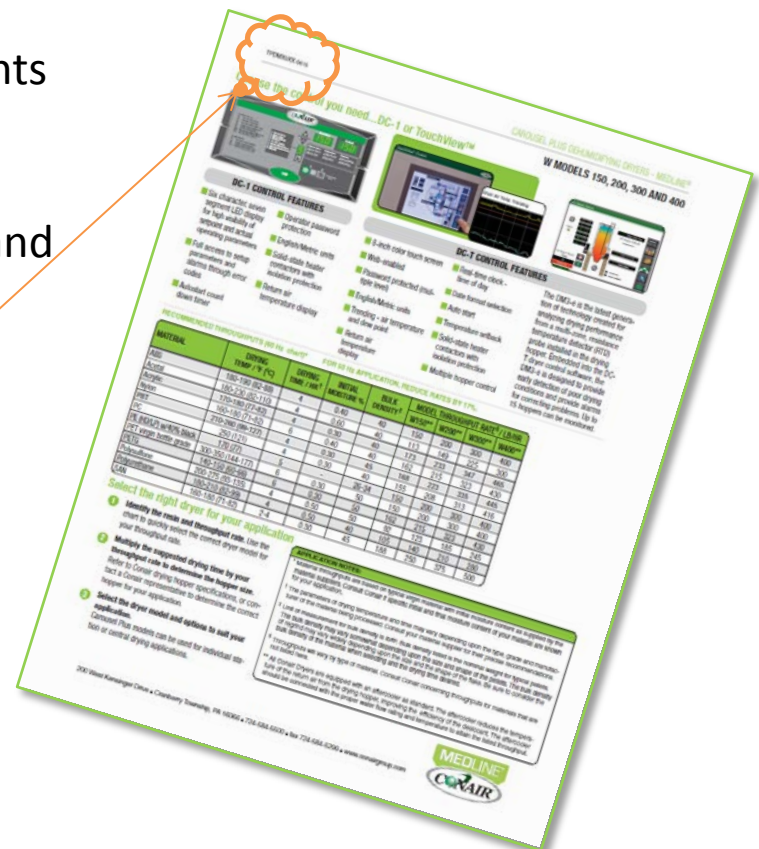
Serial Number: \_\_\_\_\_ Model: \_\_\_\_\_

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Preventative  
Maintenance  
(PM) checklist





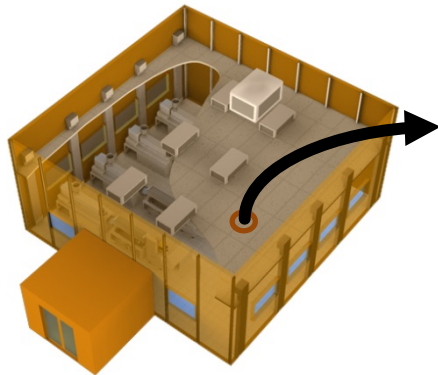
## Steps for applying MedLine equipment

### 2. Clarify MedLine compliancy:

- Exhaust minimization or elimination

A procedure to effectively deal with exhaust discharge that is primary to the operation of some equipment.

- Water-cooled chillers can be applied in place of air-cooled models.
- Vacuum valves used for resin conveying can be remote mounted outside of the clean room to discharge vacuum air.
- Additional hardware may be provided for routing moist, hot and/or particulate exhaust air from the cleanroom as required.
- Low thru-put equipment minimizes exhaust to acceptable ISO room levels.



Discharge air  
routed out of  
the cleanroom

MicroWheel  
dryer







# Steps for applying MedLine equipment

## 3. Select equipment:

Start with the MedLine brochure to understand how MedLine equipment fits your medical manufacturing requirements.







## Steps for applying MedLine equipment

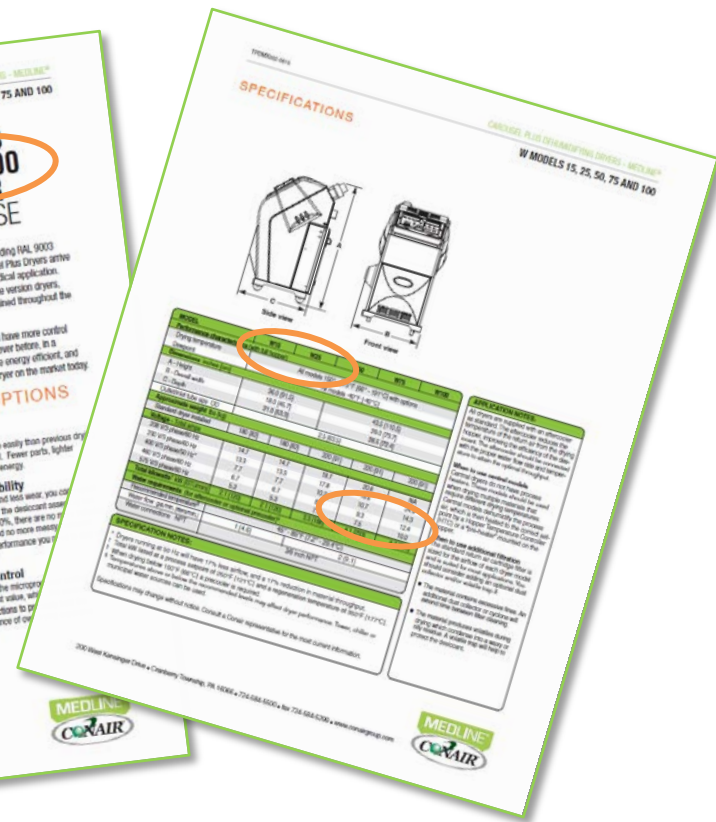
### 3. Select equipment:

MedLine brochure can be ordered from the Conair website.



The screenshot shows the Conair website's homepage. At the top left is the Conair logo with a tagline 'PATHWAYS TO PROFITABILITY'. To the right of the logo, there's a 'Choose site version:' section with flags for USA and India. Further right is a search bar and a phone number '+1.724.584.5500'. Below this is a navigation menu with links: 'About Us', 'Products', 'Support', 'Industries Served', 'Knowledge Center', 'Shop', 'NPE 2015', and 'Contact Us'. The main banner features the text 'CLEAN ROOM READY' in large, bold letters. Below this text, it states: 'Conair MedLine® auxiliary equipment is **pre-evaluated, pre-configured, pre-calibrated, fully-documented** and **ready for installation** in your clean room.' To the right of the banner is an image of MedLine equipment (a large machine and a smaller unit) with a green starburst call to action that says 'Click here to order our MedLine brochure.' The website has a blue and green color scheme.

[www.conairgroup.com](http://www.conairgroup.com)





## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine resin  
conveying







## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine  
dehumidifying dryers





## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine dehumidifying  
drying systems







## Steps for applying MedLine equipment

### 3. Select equipment:



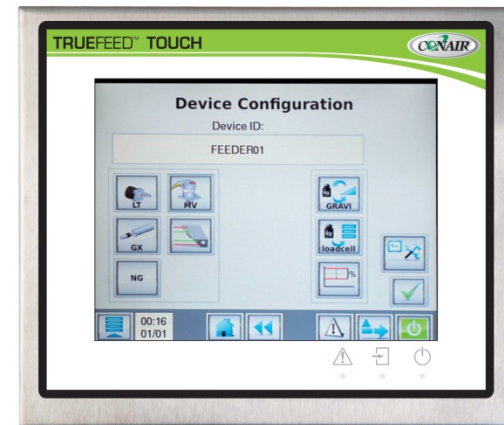
MedLine blenders





## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine throat  
metering feeders





## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine liquid  
temperature controls





## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine pipe, tubing  
extrusion







## Steps for applying MedLine equipment

### 3. Select equipment:



MedLine pipe, tubing  
extrusion



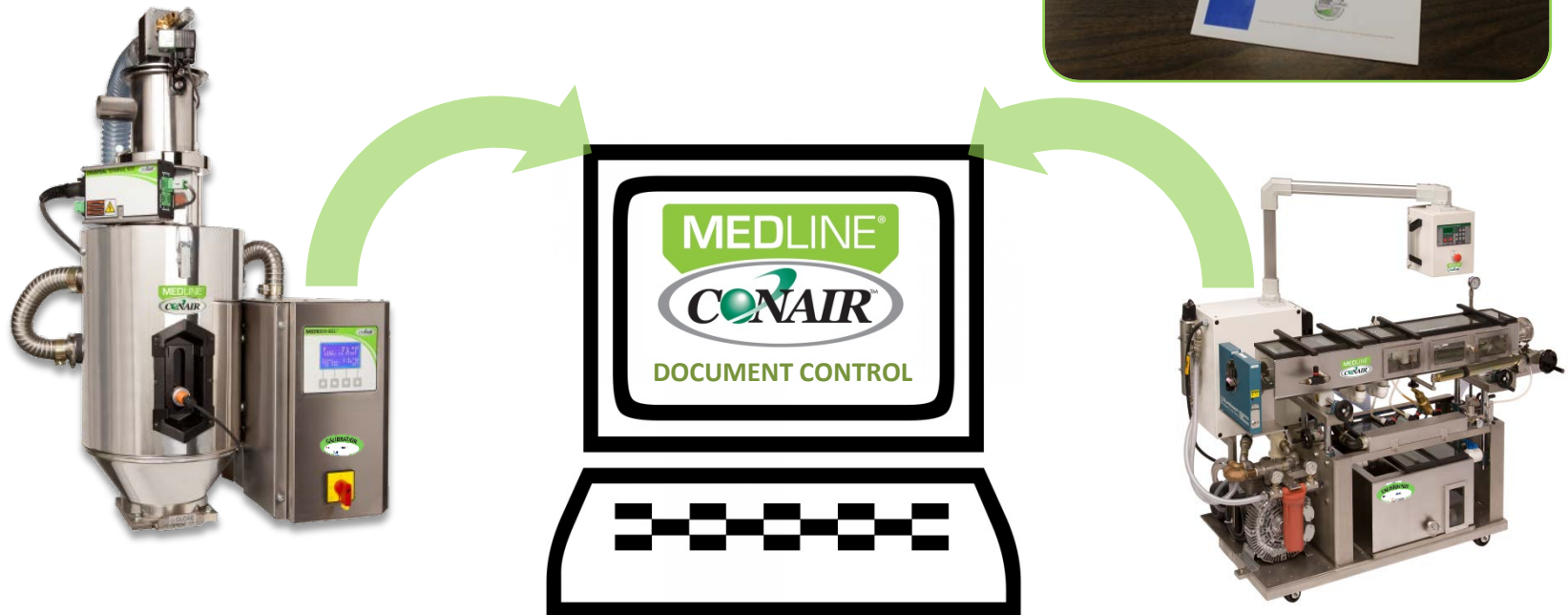




## Steps for applying MedLine equipment

### 4. Shipment/delivery:

All revision-controlled records on each piece of equipment are permanently stored for easy recall in Conair's centralized MedLine repository.



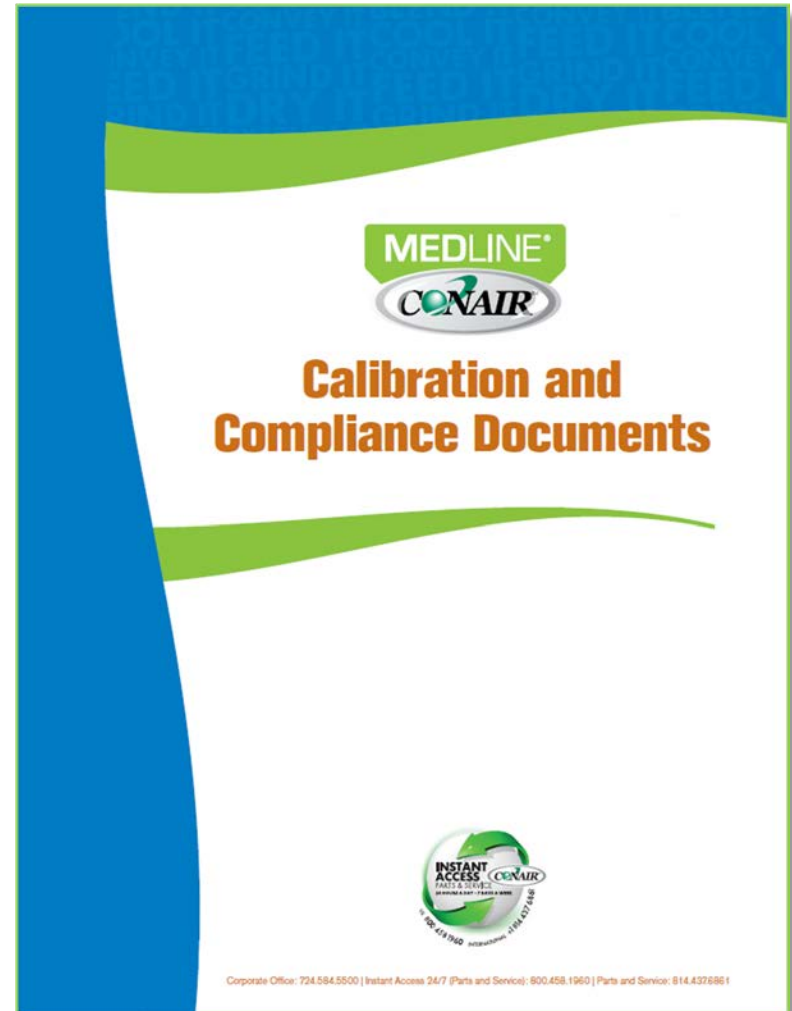


## Steps for applying MedLine equipment

### 4. Shipment/delivery:

A compliance documentation package is shipped with each piece of equipment:

- Calibration certificate
- IQ check list
- PM check list





## Steps for applying MedLine equipment

### 4. Shipment/delivery:

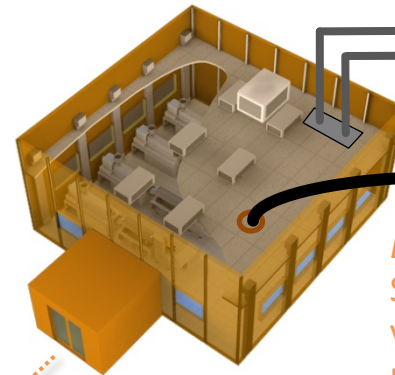
If required, Conair Project Services group can provide installation management and/or assistance:



- An experienced Project Manager, assigned to your project, provides:

- ✓ Single point of contact
- ✓ System specification
- ✓ Flow schematic
- ✓ Timeline management
- ✓ Scope-of-work documentation
- ✓ Installation drawings
- ✓ Project records

- Expert installation
- Additional design engineering if required
- Seamless integration with processing machines
- Seamless integration with clean room/infrastructure



*Examples:*  
Special bulkheads,  
vents and cable  
penetrations for clean  
rooms





## MedLine support

**A wealth of knowledge at your service:**

Meet Matt Zelkovich, Conair General Manager, Medical



724.584.5442

mzelkovich@conairgroup.com

- Over 28 years in the plastics industry. Over 10 years focused as Engineering Director of Research and Development of medical products and facility construction at:
  - West Pharmaceutical Services
  - Tech Group, Inc.
  - INTESYS Technologies
- Multiple certifications in Six Sigma Green Belt
- Executive management certificate from MIT Sloan.
- SME in Cleanroom technology

CFR?

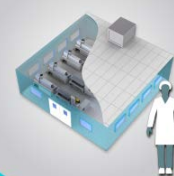


ISO?

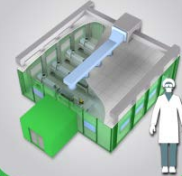
Calibration?

cGMP?

White Room



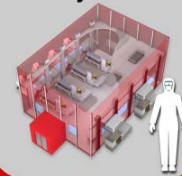
ISO 8



ISO 7



Hybrid



Your Conair representative can help with any equipment related questions.

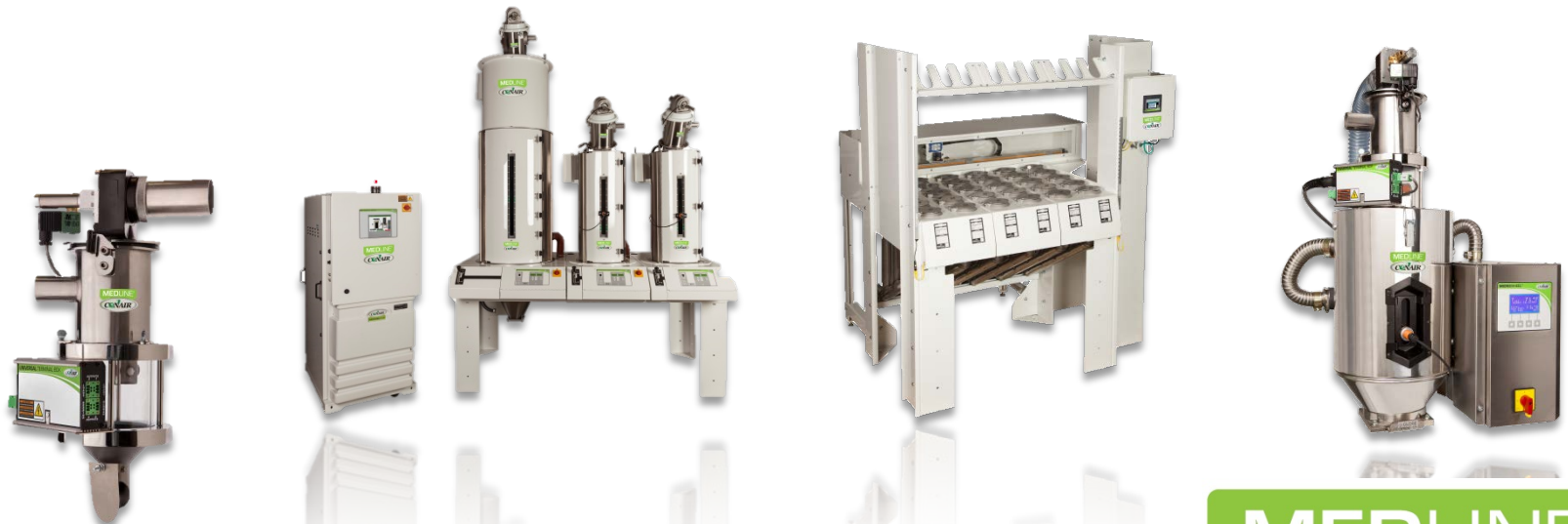
Matt and his team can help address compliance questions and issues and will be an asset to your medical manufacturing project!





# CLEANROOM READY CONAIR MEDLINE® EQUIPMENT

Thank you!



[www.conairgroup.com](http://www.conairgroup.com)

Phone: 724.584.5000

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