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TYPE OF ACTION BY THE MANUFACTURER:

We have identified and corrected the infrastructure fault and have taken measures to eliminate any residual contaminants. We have also implemented additional quality control steps to immediately detect manufacturing environmental changes.

This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. We strive to ensure our customer's experience is the best it can be; however, if you have any concerns regarding media contamination, we encourage you to contact our Technical Services department at 800.255.6730 or email microbiology.ts.us@thermofisher.com to notify our Technical Quality team.

We appreciate your immediate attention to this matter and apologize for any inconvenience this may have caused.

Sincerely,

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Gary Klaassen
Director, Quality and Regulatory Affairs

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Microbiology
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MEDICAL DEVICE FIELD ACTION NOTICE

Remel, Inc.

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