

Date: 31 Mars 2026

Avis de sécurité sur site urgent

YEASTONE BROTH, 11ML, 10/BOX (YY3462)

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*

E.mail : mbd.vigilance@thermofisher.com

Telephone: +44(0) 1256 841144

Avis de sécurité sur site (ASS) urgent

YEASTONE BROTH, 11ML, 10/BOX (YY3462)

| 1. Information on Affected Devices* | | | | | | | | | | | | |
|--|---|----------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 1. | 1. Device Type(s)* IVD | | | | | | | | | | | |
| 1. | 2. Commercial name(s) Yeastone Broth, 11ml, 10/Box <small>Click here to enter text.</small> | | | | | | | | | | | |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) 848838018817 | | | | | | | | | | | |
| 1. | 4. Primary clinical purpose of device(s)* Yeastone Broth, 11 ml, 10/Boîte (YY3462) est un test de sensibilité aux antibiotiques sur des échantillons cliniques mycologiques. | | | | | | | | | | | |
| 1. | 5. Device Model/Catalogue/part number(s)* YY3462 | | | | | | | | | | | |
| 1. | 6. Software version N/A | | | | | | | | | | | |
| 1. | 7. Affected serial or lot number range <table border="1" style="margin-left: 20px;"> <thead> <tr> <th style="text-align: center;">Numéro de lot du kit</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">321046</td></tr> <tr><td style="text-align: center;">329835</td></tr> <tr><td style="text-align: center;">330316</td></tr> <tr><td style="text-align: center;">327069</td></tr> <tr><td style="text-align: center;">330317</td></tr> <tr><td style="text-align: center;">336325</td></tr> <tr><td style="text-align: center;">338314</td></tr> <tr><td style="text-align: center;">341161</td></tr> <tr><td style="text-align: center;">303851</td></tr> <tr><td style="text-align: center;">311723</td></tr> </tbody> </table> | Numéro de lot du kit | 321046 | 329835 | 330316 | 327069 | 330317 | 336325 | 338314 | 341161 | 303851 | 311723 |
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| 321046 | | | | | | | | | | | | |
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| 341161 | | | | | | | | | | | | |
| 303851 | | | | | | | | | | | | |
| 311723 | | | | | | | | | | | | |
| 1. | 8. Associated devices N/A | | | | | | | | | | | |

| 2. Reason for Field Safety Corrective Action (FSCA)* | |
|---|---|
| 2. | 1. Description of the product problem* Remel Inc., qui fait partie de Thermo Fisher Scientific, a reçu dix réclamations de clients concernant des problèmes de performances avec Yeastone Broth, 11 ml, 10/Boîte, YY3462, lots 321046, 329835, 330316, 327069, 330317, 336325, 338314, 341161, 303851, 311723. Aucune maladie/blessure résultant de ce problème n'a été signalée. Une investigation technique interne a confirmé que les produits ci-dessous pourraient afficher des résultats d'ASAT incorrects lors du contrôle qualité. |
| 2. | 2. Hazard giving rise to the FSCA* Résultats d'ASAT incorrects lors du contrôle qualité. |
| 2. | 3. Probability of problem arising Élevé |

| | |
|----|---|
| 2. | 4. Predicted risk to patient/users Il devrait y avoir des conséquences modérées pour la santé des patients si les laboratoires ignorent les résultats des tests de contrôle qualité. D'un point de vue clinique, les tests de sensibilité aux antifongiques doivent être considérés uniquement comme une aide à l'interprétation. La probabilité que des agents antifongiques soient associés à des conséquences graves mettant en jeu le pronostic vital doit être considérée comme relativement faible, éventuellement associée à une réponse retardée ou à la nécessité de passer à un autre agent. |
| 2. | 5. Further information to help characterise the problem N/A |
| 2. | 6. Background on Issue Neuf clients ont signalé des problèmes de performances avec Yeastone Broth, 11ml, 10/Boîte, YY3462, lots 321046, 329835, 330316, 327069, 330317, 336325, 338314, 341161, 303851, 311723. |
| 2. | 7. Other information relevant to FSCA N/A |

3. Type of Action to mitigate the Risk*

| | | |
|--------------------------------|---|-------------|
| 3. | 1. Action To Be Taken by the User* <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None | |
| 3. | 2. By when should the action be completed? | Immediately |
| 3. | 3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Oui Choose an item. Examiner les résultats. | |
| 3. | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | Oui |
| 3. | 5. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None | |
| 3 | 6. By when should the action be completed? | Immediately |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? N/A Choose an item. | |
| 4. General Information* | | |
| 4. | 1. FSN Type* | New |

| | | |
|----|---|--|
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | 3. For Updated FSN, key new information as follows: | N/A |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | Pas encore prévu |
| 4. | 5. If follow-up FSN expected, what is the further advice expected to relate to: | N/A |
| 4. | 6. Anticipated timescale for follow-up FSN | N/A |
| 4. | Manufacturer information (For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Thermo Fisher Scientific |
| | b. Address | Remel Inc. 12076 Santa Fe Trail Drive PO Box 14428 Lenexa, KS 66215 |
| | c. Website address | www.thermofisher.com |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Oui | |
| 4. | 9. List of attachments/appendices: | Customer response form |
| 4. | 10. Name | Paul Sherlock |
| | Signature | |

| Transmission of this Field Safety Notice | |
|---|---|
| | <p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p> |