FSN Ref: 3013145340 -16/12/24 - 002-C **FSCA Ref: NC 336**

Terragene S.A.

XX-JAN-2025

URGENT FIELD SAFETY NOTICE (FSN)

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)

Distributor/Importer details: ASP GLOBAL MANUFACTURING GmbH ;

Device Name: BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)

Type of action: Update on Instructions for Use.

EU Authorised Representative: EMERGO Europe;

Dear Distributor,

The purpose of this notice is to inform you that Terragene S.A. has initiated a Field Safety Corrective Action (FSCA) for the product BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) (Advanced Sterilization Products brand), test pack for Steam sterilization processes which is intended for a rapid and easy monitoring of steam sterilization processes at 121-135 °C. The FSCA involves the provision of an updated Instructions for Use (IFU). This FSCA affects all BIOTRACE™ Auto Read 60 Steam BI Process Challenge Devices (73135) with version 0 of the IFU.

We have identified a discrepancy in the labeling of the affected product, which mentions in one occasion an incubation time of 20 minutes, when the correct incubation time is 60 minutes: ***"If no fluorescence is detected at 20-minute incubation, the result is negative"*** (point 9 of the Instructions for Use). We would like to inform you that this labeling error does not align with the instructions for use and could mislead users.

Based on the Health Hazard Evaluation, the likelihood that improper use of the product could cause a health risk by introducing the possibility of releasing improperly sterilized devices is considered remote. To date, Terragene is not aware of any complaints or incidents associated with the use of this product.

Terragene requests that you review your inventory records for the affected product, identify customers that received or may have received this devices and report it to Terragene, through the provided Acknowledgement and Reply Form (**Attachment 1**) via email to: customer.service@terragene.com or via mail to Terragene S.A., Head Office, Ruta Nacional n° 9, km 280, CP 2130, Parque Industrial Micropi, Alvear, Santa Fe, Argentina, within 30 days of receipt of this field safety notice.

FSN Ref: 3013145340 -16/12/24 - 002-C **FSCA Ref: NC 336**

It is important to note that the product can be used according to the updated IFU (Version 1) attached to this FSN (**Attachment 2 -** IFU BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) Rev.1).

Terragene is providing you with the updated version of the IFU and a communication for users (**Attachment 3 -** Field Safety Notice for Users and updated IFU) so that you can proceed with the proper communication to your customers who have received this product.

Please note that no additional advice or information is expected to be provided in a follow-up Field Safety Notice (FSN).

The product does not need to be returned to Terragene and can be properly used in accordance with Version 1 of the IFU. Please indicate to your customers that, once the product is opened, they must discard older versions of the IFU (version 0) in accordance with each state's regulations and use the product in accordance with the IFU version 1 available on the website (eifu.asp.com). For the products currently available in your warehouse, you may continue distribution by sending the digital FSN for users and the updated digital IFU with each delivery (**Attachment 3**). An updated printed IFU will also be made available to users upon request.

This table summarizes the distribution of the affected products:

Product and Distribution Information					
Product Name	*GTIN/ UDI-DI*	*Distribution Date (MM/DD/YYYY)*	*Lot/Serial Number*	*Expiration Date (MM/DD/YYYY)*	*Quantity*
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	05/17/2024	F40062	30/04/2026	233
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	05/16/2024	F40063	30/04/2026	318
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	05/16/2024	F40064	30/04/2026	177

Terragene®

FSN Ref: 3013145340 -16/12/24 - 002-C **FSCA Ref: NC 336**

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	05/17/2024	F40072	31/05/2026	72
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	05/17/2024	F40074	30/04/2026	140
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	06/19/2024	F40084	31/05/2026	38
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	07/22/2024	F40101	30/06/2026	113
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	08/15/2024	F40116	31/07/2026	436

If you have any concerns or require further clarification, please do not hesitate to contact us at customer.service@terragene.com, www.terragene.com or + 1 (844) 837-7243 Monday through Friday, 8:00 AM to 5:00 PM, Buenos AiresTime.

* * *

Device-related incidents may be reported to the manufacturer, distributor or local representative, and the competent authority of the State in which the user is established.

Please note that the appropriate Competent Authority has been made aware of this FSCA.

* * *

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

FSN Ref: 3013145340 -16/12/24 - 002-C **FSCA Ref: NC 336**

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

* * *

We regret any inconvenience this has caused and value the trust you place in us.

Terragene®

ATTACHMENT 1

Terragene®

FIELD SAFETY NOTICE DISTRIBUTOR/IMPORTER
Acknowledgement and Reply Form

FSN Ref: 3013145340 -16/12/24 - 002-C
FSN Date: XX-Jan-2025
Product Device name: BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) (Advanced Sterilization Products brand), test pack for Steam sterilization processes.

Distributor/Importer Information: ASP GLOBAL MANUFACTURING GmbH ;

Distributors/Importers Response:

I confirm the receipt, the reading and understanding of the Field Safety Notice. Yes _ No_

I have checked my stock consisting of _____ total units, which are listed below:

Affected Product Information Table

Product/Brand Names	*GTIN/ UDI-DI*	Lot/Serial Number shipped to Customer	Quantity in inventory	Quantity relabeled	Quantity destroyed/ returned
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40062		—	—
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40063		—	—
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40064		—	—
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40072		—	—

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40074		—	—
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40084		—	—
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40101		—	—
BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)	07798375772877	F40116		—	—

I have identified customers that received or may have received this device. Yes _ No_

I have informed the identified customers of this FSN and provided them with the updated IFU. Yes _ No_

I have received confirmation of reply from all identified customers and proof of reconciliation and effectiveness will be shared with Terragene S.A. Yes _ No_

I would like to receive paper copies of the updated IFU. Yes _ No_ Number of copies:_____

Return Response Box:

Please provide any additional information, if applicable.

Name/Title	
Signature	
Date	
Email address	

PLEASE EMAIL COMPLETED RESPONSE FORM TO: customer.service@terragene.com
OR MAIL TO: TERRAGENE SA

Head Office Ruta Nacional Nº 9 - Km 280
CP 2130 - Parque Industrial Micropi - Alvear - Santa Fe - Argentina
Phone +54 341 5587007 (08/09/10)

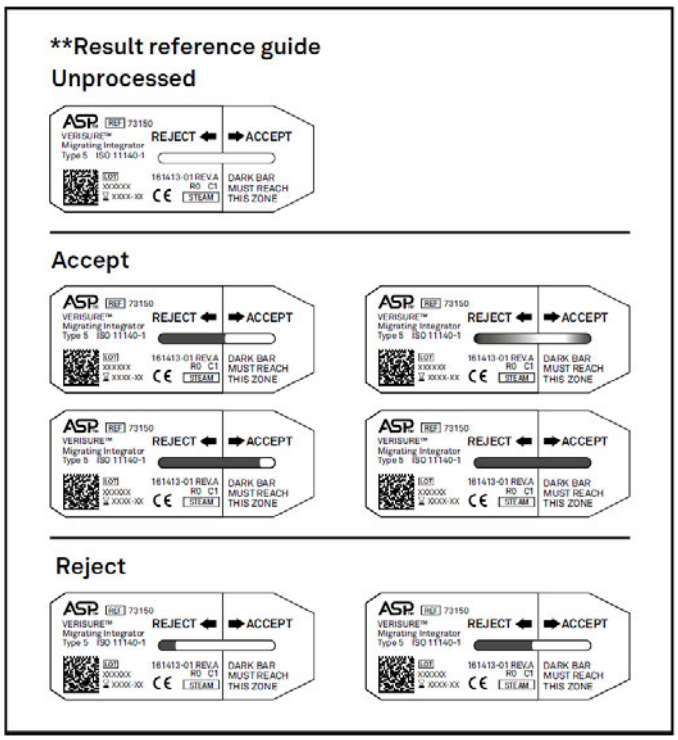
Deadline for returning the Acknowledgement and Reply Form: confirm receipt, reading and understanding of this FSN within 48 working hours and send the completed form within 30 days.

Terragene®

ATTACHMENT 2

R.01

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) for a rapid and easy monitoring of steam sterilization processes



Indications for Use

United States

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) provides a defined challenge resistance against the claimed cycles shown below and also demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack.

The device provides routine monitoring and sterilizer qualification testing steam sterilization processes. See Intended Use Table for reference.

Intended Use Table (United States)
Model 73135

Autoclave/Steam Cycles
Gravity Displacement

121 °C	132 °C	135 °C
30 min.	15 min.	10 min.
	25 min.	

Dynamic Air Removal (Vacuum Assist)

121 °C	132 °C	135 °C
NA	4 min.	3 min.

Fluorescence Read Time	**pH Color Change**
1 hour	48 hours

Outside the United States

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) has been designed for a rapid and easy monitoring of steam sterilization processes at 121-135 °C (249.8-275 °F).

Device Description

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) has been designed to simulate a load to be sterilized and to pose a challenge to the sterilization process. It is used to evaluate the effective performance of the process by detecting inadequate air removal and steam penetration. It also allows release of routine loads, especially implants. Furthermore, it allows the routine monitoring and periodic validation of the sterilizers (after repair, installation, relocation).

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) consists of a disposable pre-assembled package as outlined in ANSI/AAMI ST79 which contains a BIOTRACE™ Auto Read 60 Steam Biological Indicator (73105), a BIOTRACE™ Process Challenge Device (PCD) Record Card and a VERISURE™ Steam Type 5 Migrating Integrator (73150) (Type 5 according to ISO 11140-1:2014 standard) that gives instant visible indication that sterilizing conditions have been reached. Each pack consists of a stack of porous cards holding a Self-Contained Biological Indicator (SCBI) that contains a population of *Geobacillus stearothermophilus* ATCC® 7953 spores soaked on a carrier as well as growth indicator medium contained in a glass ampoule. Each SCBI has a process indicator (Type 1 according to ISO 11140-1:2014 standard) on label that changes from pink to brown when exposed to steam. The migrating chemical integrator shows ACCEPT result when sterilization conditions were reached while the process indicator (Type 1 according to ISO 11140-1:2014 standard) on PCD box changes from light blue to dark grey/black when exposed to steam.

Precautions

WARNING: Do not use PCD for monitoring ethylene oxide, dry heat, formaldehyde or any sterilization process other than steam. Do not reuse Biological Indicators.

WARNING: Place one or more PCDs in sterilizing hard-to-reach areas to ensure all areas of the chamber are sterilized. Evaluate all load configurations to ensure ALL hard-to-reach areas have been identified, and place a PCD in each of those locations.

WARNING: Do not reuse the sterilizer until the Biological Indicator test result is negative.

Instructions for Use

1. Place the pack inside a normally loaded steam autoclave, in those areas which are considered most inaccessible for the sterilizing agent (e.g., the center of the load and areas near the door).
2. Run the sterilization cycle.
3. After the sterilization process has finished, open the sterilizer door, wait for 5 minutes and remove the test pack. NOTE: The color of the box may vary from the original after undergoing the sterilization cycle. This does not represent a problem regarding the operation or quality of the product.
4. Check that the process indicator printed on the box has changed color from light blue to grey. Open the test pack, wait 5 minutes and remove the SCBI. Allow it to cool down to room temperature. PRECAUTION: Wear safety glasses and gloves when removing the Biological

Indicator from the sterilized test pack. WARNING: Do not crush or handle the Biological Indicator excessively, since this might cause the glass ampoule to burst.

5. Check VERISURE™ Steam Type 5 Migrating Integrator (73150) for correct exposure. If the dark bar has reached the ACCEPT zone, this confirms that the inside of the pack has been exposed to correct sterilization conditions (refer to Result Reference Guide). Otherwise, check the sterilization process.

6. Check the process indicator printed on SCBI's label. A color change to brown confirms that the Biological Indicator has been exposed to steam.

IMPORTANT: This color change does not indicate that the process was sufficient to achieve sterility.

7. Identify BIOTRACE™ Auto Read 60 Steam Biological Indicator (73105) by writing the sterilizer number (in case of having more than one), load number, and processing date on the label. Fill out the required information on the Record Card.

8. Press the cap to seal the tube. Crush the glass ampoule contained in the SCBI with an individual ampoule crusher or with the ampoule crusher placed within the incubator's incubation area. Then shake the tube down vigorously, until the medium reaches the base of the tube and soaks the spore carrier entirely. Incomplete wetting of the spore carrier may lead to an incorrect fluorescence readout. Finally, place the SCBI in the incubator. IMPORTANT: Use a non-sterilized SCBI as a positive control at least once per day, when a sterilization cycle is run. The positive control ensures that the correct incubation conditions have been followed, that the medium promotes rapid growth, that spore viability has not been compromised by improper storage temperature, humidity or proximity to chemicals, and that the BIOTRACE™ Auto Read Devices are functioning properly. Both the positive control indicator and the processed indicator should belong to the same batch.

9. Incubate the processed Biological Indicator and the indicator used as positive control in the appropriate BIOTRACE™ Auto Read Device for 60 minutes at 60 ± 2 °C (140 ± 3.6 °F) to get the final fluorescence result. NOTE: Holding time between sterilization and incubation should not exceed a 7-day period. Fluorescence detection by the Auto Read Device (excitation 340-380 nm / emission 455-465 nm) means a failure in the sterilization process. If no fluorescence is detected at 60-minute incubation, the result is negative (i.e., the sterilization process was successful). The positive control must give positive fluorescence readout. NOTE: A 48-hour readout is optional to confirm the 60-minute result by visual color change. If the sterilization process has not been successful, culture medium will turn yellow during incubation at 60 ± 2 °C (140 ± 3.6 °F). If sterilization was successful, culture medium will remain purple after incubation. It is good practice to incubate a positive control for a visual color change. The positive control must show a color change from purple to yellow for results to be valid.

10. Record the SCBI and integrator results and adhere the self-adhesive Record Card or, alternatively, only the area containing the integrator indicator. WARNING: Do not use the sterilizer until the Biological Indicator test results are negative.

11. Discard the pack and the indicators immediately, as it is indicated below.

NOTE: if any serious incident occurs in relation to the device, it should be reported to Advanced Sterilization Products, Inc. (ASP) and the competent authority of the State in which the user is established.

Monitoring frequency

Follow the policies and procedures with the monitoring frequency specified by the professional associations and/or standards corresponding to your country. As recommended practice, and to provide optimal patient safety, ASP recommends that each sterilization load be monitored with the appropriate Biological Indicator.

Storage

Store in a dark place, at a temperature between 10-30 °C (50-86 °F), 30-80 % relative humidity. Do not freeze. Do not store near sterilizing agents or other chemical products.

Shelf Life

BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) has an expiration date of 2 years from the date of manufacture, given by the SCBI that carries, when stored at recommended conditions. Do not use it after expiration date. Chemical Integrators and process indicators have an expiration date of 2 years when used in/on PCD.
End Point Stability Reaction: chemical indicator endpoint shall remain unchanged for a period of not less than 6 months when stored at previously indicated conditions.

Disposal

Discard Biological Indicators after use according to your country's healthcare and safety regulations. The positive Biological Indicators can be autoclaved in a gravity air displacement steam sterilizer at 121 °C (249.8 °F) for 30 minutes, 132 °C (269.6 °F) for 15 minutes or 134 °C (273.2 °F) for 10 minutes; or in a dynamic air removal steam sterilizer at 132 °C (269.6 °F) for 4 minutes or 135 °C (275 °F) for 3 minutes.

For a glossary of symbols used, go to eifu.asp.com

Terragene®

ATTACHMENT 3

FSN Ref: 3013145340 -16/12/24 - 002-C **FSCA Ref: NC 336**

XX/JAN/2025

URGENT FIELD SAFETY NOTICE (FSN)

Advanced Sterilization Products - BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135)

For attention of: [Identify either by name or role who needs to be aware of the hazard and/or take action]

The purpose of this notice is to advise you that Terragene S.A. has initiated a Field Safety Corrective Action (FSCA) for the product BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) (Advanced Sterilization Products brand), test pack for Steam sterilization processes, which is intended for a rapid and easy monitoring of steam sterilization processes at 121-135 °C. The FSCA involves the provision of an updated Instructions for Use (IFU). This FSCA affects all BIOTRACE™ Auto Read 60 Steam BI Process Challenge Devices (73135) with version 0 of the IFU. [UDI-DI no 07798375772877].

A discrepancy has been detected in the labeling of the affected product, which mentions in one occasion an incubation time of 20 minutes, when the correct incubation time is 60 minutes: ***"If no fluorescence is detected at 20-minute incubation, the result is negative"*** (point 9 of the Instructions for Use). We would like to inform you that this labeling error does not align with the instructions for use and could mislead users.

The likelihood that improper use of the product could cause a health risk by introducing the possibility of releasing improperly sterilized devices is considered remote. To date, Terragene is not aware of any complaints or incidents associated with the use of this product.

The product does not need to be returned and can be used according to the updated IFU (Version 1) attached to this notice (**Attachment 1 -** IFU BIOTRACE™ Auto Read 60 Steam BI Process Challenge Device (73135) Rev.1). No additional advice or information is expected to be provided in a follow-up Field Safety Notice (FSN).

Please acknowledge receipt of this communication, review your inventory records, and identify any affected product in your possession. Once the product is opened, please discard older versions of the IFU (version 0) in accordance with your state's regulations and use the product according with the IFU version 1 attached to this notice and available on the website (eifu.asp.com). If you prefer to receive the Instructions for Use in physical format, please request it when you respond to this field safety notice and you will be provided with it as soon as possible.

* * *

Device-related incidents may be reported to the manufacturer, distributor or local representative, and the competent authority of the State in which the user is established.

Please note that the appropriate Competent Authority has been made aware of this FSCA.

* * *

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

FSN Ref: 3013145340 -16/12/24 - 002-C **FSCA Ref: NC 336**

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action

* * *

If you have any concerns or require further clarification, please do not hesitate to contact ASP GLOBAL MANUFACTURING GmbH at [email and telephone number to be completed by ASP]

Name: [To be completed by ASP]
Title: [To be completed by ASP]
Signature: [To be completed by ASP]
Date: [To be completed by ASP]