

Strolenberg B.V.

FSN Ref: TT-GT-2025-FSN-JD

FSCA Ref: TT-GT-2025-FSCA-JD

ENCODE / Get Tested International AB / MEDNOSTIC / Baleamed / Thuietest.Shop

Date: 2026-03-06

**ENCODE Chlamydia & Gonorrhoea STI Test**  
**ENCODE Combo HIV and Syphilis STI Test**  
**ENCODE Chlamydia, Gonorrhoea, HIV and Syphilis STI Test**  
**ENCODE Rapid HIV Test**  
**BALEAMED HSV-1 & HSV-2 Combo Rapid Test**  
**GET TESTED HSV-1 & HSV-2 Combo Rapid Test**  
**MEDNOSTIC HSV – Herpes Simplex Virus – Type 1**  
**MEDNOSTIC HSV – Herpes Simplex Virus – Type 2**  
**ENCODE HSV – Herpes Simplex Virus – Type 2**  
**GET TESTED 8-in-1 Rapid STD Test**  
**GET TESTED Candida albicans Vaginal Test**  
**GET TESTED HPV Rapid Test**  
**GET TESTED Syphilis Test**  
**GET TESTED MPOX Test**  
**GET TESTED Blood Type Test**  
**GET TESTED Urinary Tract Infection Test**

Field Safety  
Notice:

For Attention of\*: Consumers / lay users who purchased any of the affected STI self-tests in EU

Contact details of local representative (name, e-mail, telephone, address etc.)\*  
Name: Strolenberg B.V. - ThuisTest.Shop / STDheimtest.de  
Address: Burgermeester Roelenweg 13, 8021 EV Zwolle, The Netherlands  
E-mail: [support@thuietest.shop](mailto:support@thuietest.shop) / [kundenservice@stdheimtest.de](mailto:kundenservice@stdheimtest.de)

- Frequently Asked Questions (English):  
[https://thuietest.shop/en/FAQ\\_Safety\\_Notice](https://thuietest.shop/en/FAQ_Safety_Notice)
- Meest gestelde vragen (NL):  
[https://thuietest.shop/FAQ\\_Safety\\_Notice](https://thuietest.shop/FAQ_Safety_Notice)
- Häufig gestellte Fragen (Deutsch):  
[https://thuietest.shop/de/FAQ\\_Safety\\_Notice](https://thuietest.shop/de/FAQ_Safety_Notice)
- Questions fréquemment posées (Français):  
[https://thuietest.shop/fr/FAQ\\_Safety\\_Notice](https://thuietest.shop/fr/FAQ_Safety_Notice)
- Preguntas frecuentes (Español):  
[https://thuietest.shop/es/FAQ\\_Safety\\_Notice](https://thuietest.shop/es/FAQ_Safety_Notice)

- Domande frequenti (Italiano):  
[https://thuietest.shop/it/FAQ\\_Safety\\_Notice](https://thuietest.shop/it/FAQ_Safety_Notice)
- Vanliga frågor (Svenska):  
[https://thuietest.shop/sv/FAQ\\_Safety\\_Notice](https://thuietest.shop/sv/FAQ_Safety_Notice)
- Najczęściej zadawane pytania (Polski):  
[https://thuietest.shop/pl/FAQ\\_Safety\\_Notice](https://thuietest.shop/pl/FAQ_Safety_Notice)

Submit your answer here:

<https://twrxnhzs.formester.com/f/2dbVjHTOy>

## **Field Safety Notice (FSN)**

ENCODE Chlamydia & Gonorrhoea STI Test	(6150803970964)
ENCODE Combo HIV and Syphilis STI Test	(6150825775738)
ENCODE 4-in-1 Chlamydia, Gonorrhoea, HIV and Syphilis STI Test	(6150857773702)
ENCODE Rapid HIV Test	(6150830655674)
BALEAMED HSV-1 & HSV-2 Combo Rapid Test	(7340221710047)
GET TESTED HSV-1 & HSV-2 Combo Rapid Test	(6150842163143)
MEDNOSTIC HSV – Herpes Simplex Virus – Type 1	(8720892531834)
MEDNOSTIC HSV – Herpes Simplex Virus – Type 2	(8720892531841)
ENCODE HSV – Herpes Simplex Virus – Type 2	(8720892531841)
GET TESTED 8-in-1 Rapid STD Test	(6153742096061)
GET TESTED Candida albicans Vaginal Test	(7340221700888)
GET TESTED HPV Rapid Test	(7340221708259)
GET TESTED Syphilis Test	(7340221701656)
GET TESTED MPOX Test	(7340221708976)
GET TESTED Blood Type Test	(7340221708136)
GET TESTED Urinary Tract Infection Test	(7340221700529)

Use of above devices that had been placed on the EU market without valid CE marking under the applicable IVD legislation.

### **1. Information on Affected Devices\***

1. 1. Device Type(s)*	In vitro diagnostic rapid self-tests for sexually transmitted infections, intended to be used by lay users at home for detection of certain STI markers in samples. Devices are supplied as single-use, non-sterile test kits including test cassettes and accessories.
1. 2. Commercial name(s)*	Chlamydia & Gonorrhoea STI Test Combo HIV and Syphilis STI Test 4-in-1 Chlamydia, Gonorrhoea, HIV and Syphilis STI Test Rapid HIV Test HSV – Herpes Simplex Virus – Type 1 HSV – Herpes Simplex Virus – Type 2 8-in-1 Rapid STD Test Candida albicans Vaginal Test HPV Rapid Test Syphilis Test MPOX Test

Blood Type Test  
Urinary Tract Infection Test

1. 3. Unique Device Identifier(s) (UDI-DI) No UDI-DI have been assigned, identification is ensured by trade names, SKUs and EANs.

**Product      Intended Use**

ENCODE Chlamydia & Gonorrhea STI Test

The ENCODE Chlamydia & Gonorrhea STI Test is a rapid immunochromatographic in vitro diagnostic device for the qualitative detection of Chlamydia trachomatis and Neisseria gonorrhoeae antigens in human specimens (swab). The test is intended for screening of suspected infection and provides preliminary results to aid in the detection of chlamydia and gonorrhea infection.

1. 4. Primary clinical purpose of device(s)\*
- ENCODE Combo HIV and Syphilis STI Test
- The ENCODE Combo HIV and Syphilis STI Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1/2 and Treponema pallidum (syphilis) in human whole blood, serum, or plasma. This in vitro diagnostic device is intended for the detection of HIV and syphilis infection and provides preliminary screening results.

ENCODE 4-in-1 Chlamydia, Gonorrhea, HIV and Syphilis STI Test

The ENCODE 4-in-1 STI Test is a rapid immunochromatographic in vitro diagnostic device intended for the qualitative detection of Chlamydia trachomatis, Neisseria gonorrhoeae, antibodies to HIV-1/2, and antibodies to Treponema pallidum in human swab and specimens as specified in the instructions for use. The device provides preliminary results for the screening of these sexually transmitted infections.

ENCODE  
Rapid HIV  
Test

The ENCODE Rapid HIV Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human whole blood, serum, or plasma. This in vitro diagnostic device is intended as an aid in the detection of HIV infection and provides preliminary screening results.

BALEAMED  
HSV-1 &  
HSV-2  
Combo  
Rapid Test

The BALEAMED HSV-1 & HSV-2 Combo Rapid Test is a rapid immunochromatographic assay for the qualitative detection of antibodies to Herpes Simplex Virus Type 1 (HSV-1) and Type 2 (HSV-2) in human whole blood, serum, or plasma. The test is intended as an in vitro diagnostic screening tool to aid in the detection of HSV infection.

GET TESTED  
HSV-1 &  
HSV-2  
Combo  
Rapid Test

The GET TESTED HSV-1 & HSV-2 Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HSV-1 and HSV-2 in human blood specimens. The device is intended for in vitro diagnostic use and provides preliminary results to support the detection of herpes simplex virus infection.

MEDNOSTIC  
HSV –  
Herpes  
Simplex  
Virus – Type  
1

The MEDNOSTIC HSV Type 1 Rapid Test is a rapid immunochromatographic assay intended for the qualitative detection of antibodies to Herpes Simplex Virus Type 1 (HSV-1) in human whole blood, serum, or plasma. The device is an in vitro diagnostic test intended for screening purposes.

MEDNOSTIC  
HSV –  
Herpes  
Simplex

The MEDNOSTIC HSV Type 2 Rapid Test is a rapid immunochromatographic assay intended for the qualitative detection of antibodies to Herpes Simplex Virus Type 2 (HSV-2) in human whole blood, serum, or

Virus – Type 2 plasma. The device provides preliminary results for screening of HSV-2 infection.

ENCODE HSV – Herpes Simplex Virus – Type 2 The ENCODE HSV Type 2 Rapid Test is a rapid chromatographic immunoassay intended for the qualitative detection of antibodies to Herpes Simplex Virus Type 2 (HSV-2) in human blood specimens. This in vitro diagnostic device is intended for screening purposes and provides preliminary results.

8 in 1 STI Test The GetTested 8 in 1 Genital Care Antigen Home Test Kit is a rapid chromatographic immunoassay for the qualitative detection of 1. Trichomonas vaginalis (TV), 2. Candida Antigen (CA), 3. Gardnerella vaginalis (GV), 4. Mycoplasma genitalium (MG), 5. Chlamydia trachoma (CHT), 6. Neisseria gonorrhoeae (NGH) 7. Mycoplasma hominis (MH), 8. Ureaplasma urealyticum (UU) antigens in human urine. This test is an in vitro diagnostic for screening 8 common genital infections with a self collected urine sample at home.

GET TESTED Candida albicans Vaginal Test The GET TESTED Candida albicans Vaginal Test is a rapid immunochromatographic assay intended for the qualitative detection of Candida albicans antigen in vaginal swab specimens. The device is intended for in vitro diagnostic use and provides preliminary screening results for vaginal candidiasis.

GET TESTED HPV Rapid Test The GET TESTED HPV Rapid Test is an in vitro diagnostic device intended for the qualitative detection of high-risk Human Papillomavirus (HPV) types in human cervical or vaginal specimens, as specified in the instructions for use. The test provides

preliminary screening results to aid in identifying possible HPV infection.

GET TESTED Syphilis Test The GET TESTED Syphilis Test is a rapid chromatographic immunoassay intended for the qualitative detection of antibodies to Treponema pallidum in human whole blood, serum, or plasma. The device is intended for in vitro diagnostic use and provides preliminary results for screening of syphilis infection.

GET TESTED MPOX Test The GET TESTED MPOX Test is a rapid in vitro diagnostic device intended for the qualitative detection of specific antigens associated with Monkeypox virus (Mpox) infection in human specimens as defined in the instructions for use. The test provides preliminary screening results to aid in the identification of suspected Mpox infection.

GET TESTED Blood Type Test The GET TESTED Blood Type Test is a rapid chromatographic assay intended for the qualitative determination of ABO blood group and Rh(D) factor in human whole blood. The device is an in vitro diagnostic test intended for blood type screening.

GET TESTED Urinary Tract Infection Test The GET TESTED Urinary Tract Infection Test is a rapid in vitro diagnostic test strip intended for the qualitative or semi-quantitative detection of parameters such as leukocytes, nitrite, protein, and/or blood in human urine, as specified in the instructions for use. The device is intended as a screening tool to aid in the detection of possible urinary tract infection (UTI).

	<b>Product</b>	<b>SKU/EAN</b>
	Chlamydia & Gonorrhea STI Test	6150803970964
	Combo HIV and Syphilis STI Test	6150825775738
	4-in-1 Chlamydia, Gonorrhea, HIV and Syphilis STI Test	6150857773702
	HSV-1 & HSV-2 Combo Rapid Test	6150830655674 + 6150842163143
	Rapid HIV Test	7340221710047
	Herpes Simplex Virus – Type 1	8720892531834
Device	Herpes Simplex Virus – Type 2	8720892531841
1. 5. Model/Catalogue/part number(s)*	Herpes Simplex Virus – Type 2	8720892531841
	8-in-1 Rapid STD Test	6153742096061
	Candida albicans Vaginal Test	7340221700888
	HPV Rapid Test	7340221708259
	Syphilis Test	7340221701656
	MPOX Test	7340221708976
	Blood Type Test	7340221708136
	Urinary Tract Infection Test	7340221700529

1. 6. Software version Not applicable.

1. 7. Affected serial or lot number range The FSCA applies to all lots above tests that were distributed on the market within the period: 2024-06-23 to 2026-01-31.

1. 8. Associated devices None.

**2. Reason for Field Safety Corrective Action (FSCA)\***

2. 1. Description of the product problem*	<p>During an internal regulatory review and subsequent communication with our suppliers and supervisory authorities — the Swedish Medical Products Agency (Läkemedelsverket) and the Dutch Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd) — we identified that certain GetTested-, ENCODE-, Mednostic-, and Baleamed-branded STI self-tests were placed on the Swedish and EU market without valid CE marking in accordance with the applicable IVD legislation.</p> <p>At this time, no specific manufacturing defects, analytical malfunctions, or clinical performance issues have been identified. The Field Safety Corrective Action (FSCA) has been initiated solely due to non-compliance with CE-marking and conformity assessment requirements.</p> <p>The regulatory non-compliance may lead to:</p>
2. 2. Hazard giving rise to the FSCA*	<ul style="list-style-type: none"> <li>• Use of self-tests that have not been appropriately certified for self-testing under EU IVD legislation.</li> <li>• A risk that negative or positive results may be relied upon by users without the assurance provided by a valid CE self-test conformity assessment.</li> </ul>
2. 3. Probability of problem arising	<p>No device-related incidents or complaints regarding incorrect results or harm have been reported to date. The main issue is that these self-tests have not been legally CE-marked for consumer use and/or were marketed as products intended for professional use only, as required. As a result, their performance as self-tests has not been assessed under the appropriate regulatory route.</p>
2. 4. Predicted risk to patient/users	<p>The predicted risk from continued use is considered low to moderate, depending on individual user behaviour (e.g. ignoring persistent symptoms or not seeking medical advice despite ongoing risk). By implementing this FSCA and advising users to stop using the tests and seek appropriate medical testing, the residual risk is reduced.</p>
2. 5. Further information to help characterise the problem	<p>No confirmed cases of user harm associated with above products have been reported. The FSCA is initiated due to</p>

regulatory non-compliance and is being carried out as a voluntary recall.

2. 6. Background on Issue
- Strolenberg B.V. identified, through a regulatory review and communication with the Dutch Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd), and following contact with GetTested, which is in communication with the Swedish competent authority, that the affected STI self-tests were not covered by a valid CE mark during the transition from IVDD to IVDR. Strolenberg B.V. immediately stopped the sale and marketing of the product and initiated this FSCA and the recall of all affected units upon confirmation of this issue. The root cause was an incorrect assumption and miscommunication regarding the CE-marking status of the OEM device when branding and placing it on the market.

2. 7. Other information relevant to FSCA

Corrective and preventive actions (CAPA) are being implemented to strengthen internal processes for product onboarding, regulatory review and CE-marking verification before any future products are placed on the EU market.

### 3. Type of Action to mitigate the risk\*

3. 1. Action To Be Taken by the User\*
- Identify Device  Quarantine Device  Return Device  Destroy Device
- On-site device modification / inspection
- Follow patient management recommendations
- Take note of amendment / reinforcement of Instructions For Use (IFU)
- Other  None

#### Instructions for users:

- Stop using any remaining affected STI self-tests listed above.

- If you still have unused kits, dispose of them safely with household waste in accordance with local regulations.
- If you have used these tests in the past and received a negative result but still have symptoms or remain at risk for STIs, or are uncertain about a positive result, you should consult a healthcare professional or STI clinic for appropriate testing and advice.
- If you have further concern regarding this product, you may contact us using the contact details above for further information and remedial measure.

3. 2. By when should the action be completed? 5 days upon receipt of this Field Safety Notice.

Is follow-up of patients or review of patients' previous results recommended?

3. 3. Particular considerations for: Choose an item.  
Choose an item.

Provide further details of patient-level follow-up if required or a justification why none is required.

Is customer Reply Required?  
\*  
3. 4. (If yes, form attached specifying deadline for return) Yes  
Users are requested to complete and return the attached Customer Reply Form by 2025-03-14 to confirm that they have received and understood this FSN and that the required actions have been completed.

Product Removal  On-site device modification/inspection

Software upgrade  IFU or labelling change

3. 5. Action Being Taken by the Manufacturer\*  Other  None

Strolenberg B.V. has:

- Stopped sales and distribution of the affected STI self-tests in EU markets.

- Initiated this FSCA and notification to the Dutch Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd), and contact with GetTested, which is in communication with the Swedish Medical Products Agency (Läkemedelsverket).
- Initiated internal corrective and preventive actions to prevent similar misinterpretations of CE-marking status.

3. 6. By when should the action be completed? 30 days of initiation of this FSCA.

3. 7. Is the FSN required to be communicated to the patient /lay user? Yes

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? Yes Appended to this FSN

#### 4. General Information\*

4. 1. FSN Type\* New

4. 2. For updated FSN, reference number and date of previous FSN Provide reference and date of previous FSN if relevant.

4. 3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.

4. 4. Further advice or information already expected in follow-up FSN? \* No

- |        |   |  |
|--------|---|--|
| 4. 5.  | If follow-up FSN expected, what is the further advice expected to relate to:                                    | Eg patient management, device modifications etc.   |
| 4. 6.  | Anticipated timescale for follow-up FSN   | For provision of updated advice.   |
| 4. 7.  | Manufacturer information (For contact details of local representative refer to page 1 of this FSN)              | a. Company Name Strolenberg B.V. / Burgemeester Roelenweg 13, 8021 EV Zwolle, The Netherlands<br>c. Website address <a href="https://www.thuistest.shop">https://www.thuistest.shop</a>                |
| 4. 8.  | The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | Yes, Dutch Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd), and contact with GetTested, which is in communication with the Swedish Medical Products Agency (Läkemedelsverket). |
| 4. 9.  | List of attachments/appendices:   | If extensive consider providing web-link instead.  |
| 4. 10. | Name/Signature  | Insert Name and Title here and signature below.  |

### **Transmission of this Field Safety Notice**

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)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

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

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.\*

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.