



Saragosse, le 7 mars 2025

Cher client,

Nous espérons que cette lettre vous trouve en bonne santé. Nous souhaitons vous informer d'un changement important concernant l'un de nos produits, changement qui pourrait avoir un impact sur vos activités.

En raison des nouvelles exigences réglementaires de l'Union européenne, nous avons le regret de vous annoncer que nous cesserons la commercialisation du kit CE-IVD *Genvinset® HLA B57v5*, à compter du 25 mai 2025. Nous comprenons que cette annonce puisse affecter vos opérations et tenons à vous assurer que nous restons pleinement engagés à vous accompagner durant cette transition.

Points clés concernant cette cessation:

- 1) Motif: décision interne liée à la conformité avec la nouvelle réglementation européenne (IVDR). Le kit ne présente aucun problème de conception ou de performance. Le changement est exclusivement dû aux exigences réglementaires nécessaires pour certifier le kit selon les nouvelles normes IVDR.
- 2) Produits de remplacement: nous continuerons à fabriquer ce produit sous étiquetage RUO à partir du 25 mai 2025.
- 3) Disponibilité de l'approvisionnement: nous continuerons à fournir le kit CE-IVDD jusqu'à la date de cessation (25 mai 2025).
- 4) Dernière production CE-IVD: avril 2025 (date d'expiration : 23 mois).
- 5) Utilisation après cessation: les distributeurs et utilisateurs finaux pourront continuer à vendre/utiliser leurs stocks existants (kits CE-IVDD) jusqu'à leur date d'expiration (mars 2027).

Afin de garantir que nous puissions répondre à vos besoins avant la date de cessation, nous vous prions de bien vouloir nous communiquer votre consommation estimée pour les deux prochaines années, si vous avez besoin que le produit conserve le marquage CE-IVD. Ces informations nous aideront à planifier la production d'avril et à assurer l'approvisionnement de tous les clients concernés.



Veillez trouver ci-joint trois annexes importantes nécessitant votre attention:

- I. *Formulaire d'accusé de réception*: veuillez signer et nous retourner ce document afin de confirmer votre compréhension de la situation et de ses implications pour les futures ventes de ce produit.
- II. *Formulaire de besoins en produit*: si vous souhaitez sécuriser du stock avant la date d'arrêt, veuillez compléter ce formulaire en indiquant le nombre de kits que vous souhaitez recevoir avant mai 2025.
- III. *Formulaire d'information du fabricant – MDCG 2024-16* concernant l'interruption ou l'arrêt de la fourniture de certains dispositifs médicaux et de certains dispositifs médicaux de diagnostic in vitro, ainsi que son annexe «Device Identification Table».
- IV. *Device Identification Table* (Annexe MDCG 2024-16).

Nous vous prions de bien vouloir nous retourner les deux premiers formulaires signés au plus tard le 31 mars 2025.

Nous vous remercions de votre compréhension et de votre coopération durant cette période de transition. Si vous avez des questions ou des préoccupations, n'hésitez pas à nous contacter de nouveau.

Merci pour votre confiance et votre fidélité.

Cordialement,

Noelia Cuadrado

Responsable Qualité et Conformité Réglementaire



Annexe I

FORMULAIRE D'ACCUSÉ DE RÉCEPTION

Je soussigné(e) _____, représentant _____, reconnais avoir lu et compris la notification concernant l'arrêt de commercialisation du kit *Genvinset® HLA B57v5*, qui prendra effet le 25 mai 2025.

Je comprends que:

1. Raison: décision interne liée à la conformité avec la nouvelle réglementation européenne (IVDR). Le kit ne présente aucun problème de conception ni de performance. Le changement est exclusivement dû aux exigences réglementaires relatives à la certification du kit selon la nouvelle réglementation européenne (IVDR).
2. Produits de remplacement: nous continuerons à fabriquer ce produit sous étiquetage RUO à partir du 25 mai 2025.
3. Disponibilité de la fourniture: nous continuerons à fournir le kit CE-IVDD jusqu'à la date d'arrêt (25 mai 2025).
4. Dernière production CE-IVD: avril 2025 (date d'expiration : 23 mois).
5. Utilisation après l'arrêt: les distributeurs ainsi que les utilisateurs finaux pourront continuer à vendre/utiliser leurs stocks existants (kits CE-IVDD) jusqu'à leur date d'expiration (mars 2027).

Je reconnais que ce changement affectera la disponibilité future ainsi que la commercialisation de ce produit.

Signature: _____

Date: _____

Veillez retourner ce formulaire signé à Blackhills Diagnostics Resources S.L.U. au plus tard le 31 mars 2025.



Annexe II

FORMULAIRE DE BESOIN EN PRODUITS

Nom de l'entreprise: _____

Personne de contact: _____

Email: _____

Téléphone: _____

Veillez indiquer le nombre de kits CE-IVD *Genvinset® HLA B57v5* dont vous aurez besoin avant la date d'arrêt du 25 mai 2025:

Nombre de kits requis:

- *Genvinset® HLA B57v5* - 24 test:
- *Genvinset® HLA B57v5* - 48 test:

Instructions spéciales ou commentaires : _____

En signant ce formulaire, je confirme que les quantités indiquées ci-dessus correspondent au nombre de kits *Genvinset® HLA B57v5* requis avant leur arrêt de commercialisation. Nous comprenons que Blackhills Diagnostic Resources S.L.U. utilisera ces informations pour la planification de la production. **La commande officielle du distributeur (Purchase Order – PO) doit être jointe à cette annexe.**

Signature: _____

Date: _____

Veillez retourner ce formulaire signé à Blackhills Diagnostic Resources S.L.U. au plus tard le 31 mars 2025.



Annex III

MANUFACTURER INFORMATION FORM ON INTERRUPTION OR DISCONTINUATION OF SUPPLY OF CERTAIN MEDICAL DEVICES AND CERTAIN *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

MDCG 2024 -16

MDCG 2024 – 16

Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain *in vitro* diagnostic medical devices (as per Article 10a of Regulation (EU) 2024/1860 amending Regulation (EU) 2017/745 and Regulation (EU) 2017/746)

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Note: this form should be completed when reporting on individual or several devices of the same manufacturer. For reporting on several devices, only one form should be completed and see section 6 for further instruction. See also Q.11 and Q.12 of ['Q&A Obligation to inform in case of interruption or discontinuation of supply'](#). For the purposes of this form, no personal data should be submitted or collected, including contact details.

1 Administrative information	
Name of National Competent Authority (NCA) to which this report is sent	Agencia Española de Medicamentos
Type of information	
<input checked="" type="radio"/> Initial information	
<input type="radio"/> Additional information (voluntary)*	
<input type="radio"/> Follow-up information (voluntary)*	
*Please specify modified sections of the form (if additional or follow-up information):	
Date of information	04/03/2025
Reference number assigned by the manufacturer (if any)	01/25
Reference number assigned by NCA (as applicable)	

2 Information on submitter of the report	
Status of submitter	
<input checked="" type="radio"/> Manufacturer	
<input type="radio"/> Authorised Representative (if mandated to act on behalf of the manufacturer)	
<input type="radio"/> Other entity (if acting on behalf of the manufacturer)	

3 Manufacturer Information	
Manufacturer organisation name Blackhills Diagnostic Resources S.L.U.	
Single registration number (if filled here and already EUDAMED registered, please leave following fields in this section 3 open) ES-MF-000001091	
Address Camino del Pilón 86, Casa 7, Local	
Postcode 50011	City Zaragoza
Phone +34 976 094 603	Fax -
E-mail n.cuadrado@bdrdiagnostics.com	Country Spain



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4 Authorized Representative Information (if applicable)	
Authorised representative organisation name (if mandated to make this report on behalf of the manufacturer)	
Single registration number (if filled here and already EUDAMED registered, please leave following fields in this section 4 open)	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5 Other entity (if applicable)	
Organisation (if completing this report on behalf of the manufacturer)	
Address	
Postcode	City
Phone	Fax
E-mail	Country

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6 Medical device information	
Risk class of device	
MDD/AIMDD <ul style="list-style-type: none"> <input type="radio"/> AIMD Active implant <input type="radio"/> MDD Class III <input type="radio"/> MDD Class IIb <input type="radio"/> MDD Class IIa <input type="radio"/> MDD Class I <input type="radio"/> MDD Class I sterile <input type="radio"/> MDD Class I measuring function 	IVDD <ul style="list-style-type: none"> <input type="radio"/> IVD Annex II List A <input checked="" type="radio"/> IVD Annex II List B <input type="radio"/> IVD for self-testing <input type="radio"/> IVD general

MDR <ul style="list-style-type: none"> <input type="radio"/> Class III <input type="radio"/> Class IIb <input type="radio"/> Class IIa <input type="radio"/> Class I <input type="radio"/> Class I sterile <input type="radio"/> Class I measuring function <input type="radio"/> Class I reusable surgical instruments 	IVDR <ul style="list-style-type: none"> <input type="radio"/> Class D <input type="radio"/> Class C <input type="radio"/> Class B <input type="radio"/> Class A <input type="radio"/> Class A sterile
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Device Identification	
<p>Please fill this section when reporting on an individual device.</p> <p>Where reporting on several devices, complete the ‘MDCG 2024-16 Annex - Device Identification Table’.</p> <p>Reports on several devices should be for the same manufacturer, the same interruption or discontinuation and same associated reason (See ‘reasons’ in section 7).</p>	
Unique Device Identification (UDI-DI)/EUDAMED ID (if applicable)	See MDCG 2024-16 Annex - Device Identification Table
Basic UDI-DI/Eudamed-DI (if applicable)	
<p>If the above UDI section is completed and the device is already registered in EUDAMED, please leave the following fields blank and go to ‘Intended use’ field.</p> <p>If filling out the following fields for devices without UDI-DI/ EUDAMED DI, please complete all mandatory fields.</p>	
Model	Catalogue/reference number
Nomenclature system (e.g. EMDN)	Nomenclature code
Nomenclature text	
Commercial name/ brand name / proprietary or common name	
Intended use according to the IFU or add IFU in attachment (voluntary)	



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7 Description of the Interruption or discontinuation of supply (information requested as per Art 10a) <i>Specify if the report concerns an interruption or discontinuation</i>
<input type="radio"/> Interruption <input checked="" type="radio"/> Discontinuation
Reason for the Interruption or Discontinuation of Supply please select: <input checked="" type="radio"/> Regulatory issue <input type="radio"/> Supply chain issue <input type="radio"/> Manufacturing issue <input type="radio"/> Other <div style="border: 1px solid black; height: 40px; width: 100%;"></div>
Additional information on reason for the interruption or discontinuation of supply (voluntary) The discontinuation of the product is due to the expiration of the CE certificate under Directive 98/79/EC (IVDD) that covers this product. Since it was previously classified as a List B product under Annex II, requiring the involvement of a notified body, and is now classified under Regulation 2017/746 (IVDR) as a Class C Companion Diagnostic, re-certifying it under IVDR would require signing an agreement with the notified body before September 2025 and undergoing a conformity assessment exclusively for this product. This process would involve not only the notified body but also the European Medicines Agency. Given the current sales volume and market price of the product, we cannot afford that cost.
Information on the assessment of the situation (If available) <input checked="" type="radio"/> Device used in a serious, acute or chronic pathology, life- sustaining or life-saving device or accessory <input type="radio"/> Intended for a specific population (e.g., vulnerable populations such as paediatric or geriatric patients) <input type="radio"/> Disruption or interruption limiting / preventing the patients from accessing treatment <input type="radio"/> Device without or with limited available alternatives, or consumable device not replaceable by any other type/ <input type="radio"/> brand Major market share in one or several members states <input type="radio"/> Other
Additional information on the assessment of the situation (if available) <small>The product is intended for testing patients with HIV that are going to start a pharmacological treatment. We are reporting this situation of discontinuation of supply, although we believe that this discontinuation reasonably foreseeable could not result in serious harm or in a risk of serious harm to patients or public health in one or more Member States, since there are other alternative genotyping methods focused on B*57:01 biomarker. However, we do want to highlight the existence of products on the market that are not specifically intended for performing the B*57:01 genotyping test and its relationship with the drug abacavir. For example, full genotyping of the HLA-B locus using SSO or NGS. These technologies are not specifically designed for detecting the HLA-B*57:01 allele and its relationship with abacavir, but laboratory users will utilize them for this purpose. Such products will be classified as Class C under IVDR but not as "Companion Diagnostic," which will significantly reduce the time and cost of (re)certification. This puts us at a competitive disadvantage, and despite our product being specifically designed for the determination of the relevant alleles, it will not remain on the market. Products like ours would undergo a series of analytical and clinical performance tests specifically designed to evaluate the clinical utility of the product. However, these tests will not be conducted for full HLA genotyping products that are not classified as Companion Diagnostic. The tests are as follows: - Clinical performance study as per Annex XIII, section 2 of the IVDR, including performance studies of the reagent with real samples in a clinical environment. - Interferents study taking into account medicines taken by the patients for which B*57:01 determination is relevant (HIV patients).</small>
Duration When is the interruption/discontinuation of supply estimated to start? Discontinuation: 26th May 2025
When is the interruption estimated to end (if available)? N/A
<i>Note: Where the estimated start date differs in case of reporting on several devices, please complete the dedicated field in the 'MDCG 2024-16 Annex - Device Identification Table'. The same applies for interruptions where end date is provided.</i>
Additional information about the estimated duration, if the start date and the duration is disclosed (voluntary):
Estimated point in time for resumption of supply of the devices (where known and appropriate)



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The medical device is usually marketed and supplied to the following countries: (voluntary)

All EEA, Turkey and Northern Ireland

AT BE BG CY CZ DE DK EE ES FI FR GR HR

HU IE IS IT LI LT LU LV MT NL NO PL PT

RO SE SI SK TR XI

Others: The code XI is used for Northern Ireland

The countries that are impacted by the interruption/discontinuation:

All EEA, Turkey and Northern Ireland

AT BE BG CY CZ DE DK EE ES FI FR GR HR

HU IE IS IT LI LT LU LV MT NL NO PL PT

RO SE SI SK TR XI

Others: The code XI is used for Northern Ireland

Information Notification(s) regarding the interruption or discontinuation of supply have been sent:

Notification to HI/HCPS	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)
Notification to AR	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)
Notification to importers	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY)
Notification to distributors	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable	Date Sent (DD/MM/YY) 04/03/25

Attached files (Voluntary)

8 Additional information on Interruption or Discontinuation of Supply (voluntary)
This section allows manufacturer, on voluntary basis or on the request of a competent authority, to share additional information

Possible mitigations measures: *to reduce the impact of the interruption or discontinuation of supply.*

Is the redistribution of EU or Global stocks an option? Yes No

Do you manufacture a similar alternative product with a similar intended purpose? Yes No

Details of the remaining inventory / existing stock level at EU level

If applicable, please provide information in attached file

Progress update on the interruption or discontinuation of supply

