EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 588493**

Issued To: **Blackhills Diagnostic Resources S.L.U**
Camino del Pilón, 86
Casa 7
Zaragoza
50011
Spain

In respect of:

Design and manufacture of kits to detect HLA A, B and DR alleles by RT - PCR

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-11-14** Date: **2022-02-01** Expiry Date: **2025-05-26**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance

Supplementary Information to CE 588493

Issued To:

Blackhills Diagnostic Resources S.L.U
Camino del Pilón, 86
Casa 7
Zaragoza
50011
Spain

Number	Device Name	Intended use per IFU
Annex II List B		
IVD 0306	GENVINSET HLA A29 GENVINSET B27 GENVINSET HLA BEHÇET'S DISEASE GENVINSET HLA DIABETES MELLITUS T1	Kits for the determination of HLA detection by PCR real-time for predisposition of genetic diseases
IVD 0306	GENVINSET B57	Kits for the determination of HLA detection by PCR real-time for pharmacogenomics

First Issued: **2012-11-14** Date: **2022-02-01** Expiry Date: **2025-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 588493**
Date: **2022-02-01**
Issued To: **Blackhills Diagnostic Resources S.L.U**
Camino del Pilón, 86
Casa 7
Zaragoza
50011
Spain

Date	Reference Number	Action
14 November 2012	7855404	First Issue.
30 January 2013	7943949	Amendment to company name to include "S.L.".
13 October 2016	8535850	Amendment to include a new manufacturing site.
24 October 2017	8849626	Certificate renewal. Amendment to include a manufacturing site move.
22 November 2018	9645697	Removal of the subcontractor Laboratory of Histocompatibility and Immunology for Research.
08 February 2019	588493	Traceable to NB 0086.
09 November 2020	3269010	Update to legal manufacturer name from Blackhills Diagnostic Resources S.L. to Blackhills Diagnostic Resources S.L.U. Removal of subcontractor Blackhills Diagnostic Resources S.L. at CIEM Zaragoza, Avenida de la Autonomía 7, Zaragoza, 50003, Spain.
Current	3581095	Certificate renewal.