

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 748704 R000

Manufacturer: Blackhills Diagnostic Resources, S.L.U

Address:

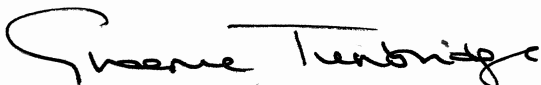
Camino del Pilón, 86
Casa 7
Zaragoza
50011
Spain

Single Registration Number: ES-MF-000001091

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-07-24**

Current Issue Date: **2023-07-24**

Starting Validity Date: **2023-07-24**

Expiry Date: **2028-07-23**

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Device Schedule: Class D, C and B devices

Class C devices

W0106 – Genetic testing
IVP3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)

Intended purpose

In vitro diagnostic reagents based on PCR tests to determine predisposition or aid in the diagnosis of genetic conditions.



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3425518	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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