

EU Quality Management System Certificate

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

IVDR 821757 R000

Manufacturer: BioSystems Diagnostics Private Limited

Address:

Plot No. A4, SIPCOT Industrial Park
Irungattukottai
Sriperumbudur Taluk 602 105
Kancheepuram District
Tamil Nadu
India

Single Registration Number: IN-MF-000013528

EU Authorised Representative: BioSystems S.A.

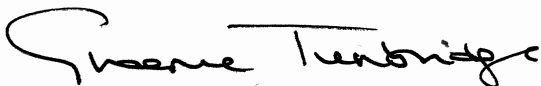
Address:

Costa Brava, 30
08030, Barcelona
Spain

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 Global Regulatory & Quality

First Issue Date: **2026-07-10**

Current Issue Date: **2026-07-10**

Starting Validity Date: **2026-07-10**

Expiry Date: **2031-07-09**

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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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Device Schedule: Class D, C and B devices

Class B devices	Intended purpose
IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers	In vitro diagnostic devices intended to be used for screening, determination or monitoring of physiological markers



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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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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	30340687	Issued



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