EU Quality Management System Certificate

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

IVDR 740169 R000

Manufacturer: Adaptive Biotechnologies Corp

Address:
1165 Eastlake Ave E
Seattle
Washington
98109
USA

Single Registration Number: US-MF-000029850

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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: **2024-06-25**

Current Issue Date: **2024-11-06**

Starting Validity Date: **2024-11-06**

Expiry Date: **2029-06-24**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0106- Genetic Testing IVP 3011- In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	Polymerase chain reaction (PCR) and Next Generation Sequencing (NSG) device, including software, used to determine measurable/minimal residual disease (MRD) and monitors changes in disease burden during and after treatment in patients diagnosed with B-cell malignancies.

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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
2024-06-25	3330630	Issued
Current	30285797	Amended – Updated manufacturer name to add "Corp". Updated manufacturer zip code to 98109. Added manufacturer SRN, US-MF-000029850.

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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.

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 389 Chiswick High Road, London, W4 4AL, UK.
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