EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 739496 R000

Manufacturer: Abionic SA

Address:
Route de la Corniche 5
CH-1066 Epalinges
Switzerland

Single Registration Number: Not Available

EU Authorised Representative: Medidee Services (Deutschland) GmbH

Address:
Hohnenweg 9
D-78098
Triberg im Schwarzwald
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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 Issued: **2022-07-19** Date: **2022-07-19** Expiry Date: **2027-07-18**

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Device Schedule:

Intended Purpose:
The IVD CAPSULE PSP is a single use, rapid in vitro diagnostic test for the quantitative measurement of pancreatic stone protein (PSP) in human capillary whole blood as well as in K2-EDTA, K3-EDTA and lithium heparin anticoagulated venous whole blood. The IVD CAPSULE PSP is to be used with the abioSCOPE 2.0 in vitro diagnostic test system. The system is intended for professional use in clinical laboratory settings or point of care (PoC) locations including near-patient testing.
The IVD CAPSULE PSP is used in conjunction with other clinical assessments and laboratory findings to aid in the early recognition of sepsis in adults.

Indications and intended patient groups:
The IVD CAPSULE PSP is intended to be used as a near patient test as an aid in the early recognition of sepsis in adults.

Risk Classification: Class C near patient-test

Type (Codes as per (EU) 2017/2185): IVR 0506

Device Name	Model	Basic UDI-DI
IVD CAPSULE PSP	P02.00026	7649996894P02CNN

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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	3326515	Issued.

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