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 575391**

Issued To: **DiaMetra S.r.l.**
Via Pozzuolo, 14
Spello (PG)
06038
Italy

In respect of:

Design and manufacture of in vitro diagnostic test kits to detect free PSA and total PSA by Immunoassay.

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: **2011-08-24** Date: **2021-08-04** Expiry Date: **2024-05-26**

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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.

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Supplementary Information to CE 575391

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Device code	Device name	Intended Purpose per IFU
Annex II List B		
IVD 0307	Total PSA (DKO137)	Immunoassays for the detection of total PSA.
IVD 0307	Free PSA (DKO138)	Immunoassays for the detection of free PSA.

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