

# 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:

**The manufacture and distribution of Diametra Free PSA and Diametra Total PSA in vitro diagnostic kits**

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **24 August 2011**

Date: **15 August 2016**

Expiry Date: **23 August 2021**

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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.