AusDiagnostics

Multiplexed Diagnostics | Affordable Healthcare

2 November 2016

Advisory Notice - CE marking of panels containing Chlamydia and CMV

AusDiagnostics is now certified by the Notified Body TUV SUD to EN ISO 13485:2012 + AC: 2012 and the Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), which allows us to CE mark IVDs for Chlamydia and CMV.

Please find the products affected, and details of the change below:

Name of products affected:

- Urinogenital (8-well) REF 27113 VER 03
- Herpes, Enterovirus and Adenovirus (8-well) REF 27091 VER 08
- Pneumonia (16-well) REF 20631 VER 03

Regulatory status of updated products: **IVD use in Australia and Europe**

Date effective of change: 4th **November 2015**

Please don't hesitate to contact us on 02 96988030 or at support@ausdx.com if you have any further queries or require any assistance with the update procedure.

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