

# Declaration of Conformity

<b>Company:</b>	<b>GENOMICA, S.A.U.</b> Parque Empresarial Alvento Edificio B.Vía de los Poblados, 1 -1 <sup>a</sup> planta. 28033 Madrid
<b>Product:</b>	<b>CLART<sup>®</sup> STDs</b>
<b>Classification:</b>	List B according to Annex II of the Directive 98/79 / EC.
<b>Conformity assessment route:</b>	Annex IV of the Directive 98/79/CE (Total Quality Guarantee System).
<b>GMDN Code</b>	50409

Genomica, S.A.U, declares that the diagnostic device *CLART<sup>®</sup> STDs*, conforms to the relevant provisions of the EC Council Directive 98/79/EC on in vitro diagnostic medical devices, transposed to the Spanish legislation in the Royal Decree 1662/2000 of 29<sup>th</sup> September 2000.

<b>Standards applied</b>	ISO 9001:2015, ISO13485:2016, ISO 14971:2012, ISO 18113-1:2011, ISO18113-2:2011, ISO18113-3:2011, EN 15223-1:2016, EN 13612:2002/AC 2002, ISO 23640:2015, EN 62304:2006, EN 61010-2-101: 2002, EN 61326-2 6:2006.
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<b>Notified Body</b>	Agencia Española de Medicamentos y Productos Sanitarios (0318)
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**EC Certificate**

<b>Period of validity</b>	From <b>21-11-2017</b> to <b>16-07-2019</b>
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Name:	Dra. Rosario Cospedal
Position:	Managing Director
Date:	Madrid, 3rd October 2017