

Declaration of Conformity

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

Genomica, S.A.U, declares that the diagnostic device *CLART® 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 29th September 2000.

Standards applied	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.
Notified Body	Agencia Española de Medicamentos y Productos Sanitarios (0318)
EC Certificate	
Period of validity	From 21-11-2017 to 16-07-2019

Name:	Dra. Rosario Cospedal
Position:	Managing Director
Date:	Madrid, 3rd October 2017