Declaration of Conformity

Company:	**GENOMICA, S.A.U.** Parque Empresarial Alvento Edificio B.Vía de los Poblados, 1 –1ª planta. 28033 Madrid
Product:	***CLART® ENTHERPEX***
Classification:	List B According to Annex II of Directive 98/79/EC.
Conformity assessment route:	Annex IV of Directive 98/79/EC (Full Quality Assurance System).
GMDN code	30798

Genomica, S.A.U, declares that the diagnostic device *CLART® ENTHERPEX*, 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 nº	2009 07 0632 CT
Period of validity::	From 21/04/2016 to 16/07/2019

Authorised signatory

Name:	Dra. Rosario Cospedal
Position:	Managing Director
Date	Madrid, 22nd November 2017

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