EC Declaration of Conformity

Company	**GENOMICA, S.A.U.** Parque Empresarial Alvento, Edificio B Calle Vía de los Poblados, 1 – 1ª planta 8033 Madrid, España
Product:	***autoclart®plus***
Classification:	Other products
Conformity assessment route:	Annex III of Directive 98/79/EC (EC Declaration of Conformity).
GMDN Code	57852

Genomica, S.A.U, declares that the diagnostic device autoclart® *plus* 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	EN ISO 9001:2008, EN ISO 13485:2016. EN ISO 14971:2012. EN 15223-1:2016, EN 13612:2002. EN ISO 18113-3:2011, EN 62304:2006. EN 61010-2-101:2002. EN 61326-2-6:2006
Notified Body	NA
EC Certificate	NA
Period of validity:	NA

Authorised Signatory

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

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