Declaration of Conformity

Company	**GENOMICA, S.A.U.** Parque Empresarial Alvento Edificio B.Vía de los Poblados, 1 -1ª planta. 28033 Madrid
Product:	***CLART® CMA NRAS i-KRAS***
Classification:	Other products
Conformity assessment route:	Annex III of Directive 98/79/EC (EC Declaration of Conformity).
GMDN Code	58280

Genomica, S.A.U, declares that the diagnostic device *CLART® CMA NRAS i-KRAS* 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	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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