

# Declaration of Conformity

GENOMICA, S.A.U. Registro Mercantil de Madrid, Tomo 404, Folio 174, Hoja nº M7906, Inscripción 1ª, Fecha 05-11-90- C.I.F. A-79434718

<b>Company</b>	<b>GENOMICA, S.A.U.</b> Parque Empresarial Alvento Edificio B. Vía de los Poblados, 1 -1ª planta. 28033 Madrid
<b>Product:</b>	<b>CLART® HUMAN PAPILOMAVIRUS 4</b>
<b>Format:</b>	<b>CLART® HPV 4S</b>
<b>Classification:</b>	Other products
<b>Conformity assessment route:</b>	Annex III of Directive 98/79/EC (EC Declaration of Conformity)
<b>GMDN Code</b>	49997

Genomica, S.A.U, declares that the diagnostic device *CLART® HUMAN PAPILOMAVIRUS 4*, 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.
<b>Notified Body</b>	NA
<b>EC Certificate</b>	NA
<b>Period of validity:</b>	NA

## Authorised Signatory

Name:	Dra. Rosario Cospedal
Position:	Managing Director
Date	Madrid, 22 <sup>th</sup> November 2017