

# Declaration of Conformity

<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® ENTEROBAC</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>	47381

Genomica, S.A.U, declares that the diagnostic device *CLART® ENTEROBAC*, 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 9001:2008, ISO13485:2012, ISO 14971:2012, ISO 18113-1:2011, ISO18113-2:2011, ISO18113-3:2011, EN 980:2008, EN 13612:2002/AC 2002, ISO 23640:2015, EN 62304:2006, EN 61010-2-101: 2002, EN 61326-2 6:2006.
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<b>Notified Body</b>	NA
<b>EC Certificate</b>	NA
<b>Period of validity:</b>	NA

Authorised Signatory

<b>Name:</b>	Dra. Rosario Cospedal
<b>Position:</b>	Managing Director
<b>Date</b>	Madrid, 13 <sup>th</sup> October 2015