

EC Declaration of Conformity

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| Company | GENOMICA, S.A.U. Parque Empresarial Alvento, Edificio B Calle Vía de los Poblados, 1 – 1ª planta 8033 Madrid, España |
| Product: | CAR® (CLINICAL ARRAY READER) |
| Classification: | Other products |
| Conformity assessment route: | Annex III of Directive 98/79/EC (EC Declaration of Conformity). |
| GMDN Code | 57862 |

Genomica, S.A.U, declares that the diagnostic device *CAR® (CLINICAL ARRAY READER)* 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.

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| 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 |
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| Notified Body | NA |
| EC Certificate | NA |
| Period of validity: | NA |

Authorised Signatory

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