EC Declaration of Conformity

Manufacturers Name: Juno Genetics España S.L.

Manufacturers Address: Ronda Guillermo Marconi 11-A, 1°22B,
46980 Paterna, Valencia, Spain

SRN (Single Registration Number): ES-MF-000045150

Basic UDI-DI: **843026899EBKE9**

Name of the Device(s): **EMBRYO BIOPSY KIT**

Product Code:	Model	UDI-DI
FL1026	10 tubes	8437026899004
FL1054	60 tubes	8437026899028

Basic UDI-DI: **8437026899EBWBAF**

Name of the Device(s): **EMBRYO BIOPSY WASH BUFFER**

Product Code:	Model	UDI-DI
RE1361	6 tubes	8437026899011

Intended Purpose: The EMBRYO BIOPSY KIT and the EMBRYO BIOPSY WASH BUFFER are in vitro diagnostic medical devices intended to be used in combination for the collection, preservation, and transport of embryonic biopsy samples (trophectoderm cells) from patients being investigated for suspected embryonic genetic conditions. The collected biopsy samples are meant for subsequent analysis using Preimplantation Genetic Testing. The devices are intended to be used as part of a diagnostic workflow with the PGT processes, aiding in identifying viable embryos for implantation.

Classification: Class A (no sterile)

Notified Body: Not applicable

Conformity Assessment route: (EU) 2017/746, Annex IV

This declaration of conformity is issued under the sole responsibility of Juno Genetics España S.L. We hereby declare that the in vitro diagnostic medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by the certification body "SGS International Certification Services Ibérica, S.A". All supporting documentation is retained at the premises of the manufacturer.

Place and Date of issue: Paterna (SPAIN); 2026-01-26

[Carlos Marín Vallejo, Technical Responsible]

[Blas Cuallado Gascó, PRRC]