

DECLARATION

We, VITROMED GmbH, herewith declare as a manufacturer in Germany that the following products are registered for sale in the US.

510(k) exempt products:

Product	Variant
V-ICSIPET	V-ICSIPET HOLDING V-ICSIPET INJECTION (with and without spike) V-ICSIPET POLAR BODY BIOPSY V-ICSIPET BLASTOMERE BIOPSY V-ICSIPET TROPHECTODERM BIOPSY V-ICSIPET ZONA DRILLING / ASSISTED HATCHING V-ICSIPET ZONA CUTTING

They can be marketed in USA and there are no restrictions to sell these products legally in USA. For further information, please check FDA database and type in VITROMED as Owner/ Operator to find products (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>).



Dr. Franziska Buch
Director of Operations / Authorized representative