

Product: **EmbryoSlide Polara 16**

Catalogue No.: 16431

Lot No.: 16-P8-2602-1

Manufactured: February 2026

We hereby confirm that the LOT indicated above will be validated in accordance with the following tests. Before final release for distribution the product has to pass all tests with acceptable results:

Sterility Sterility is obtained through irradiation according to ISO 11137 with SAL 10^{-6} . Caution: Only contents of unopened or undamaged packages are guaranteed sterile.

Cytotoxicity The product has successfully passed cytotoxicity testing in accordance with the USP, Method <87> and ISO 10993-5.

Embryo toxicity Blastocyst formation rate larger than 80% for fully expanded blastocysts both in test and control after 96 hours. The embryo toxicity test is a release test and the product will only be sold if it has passed satisfactorily.

The product is CE Marked according to the Medical Device Regulation (EU) 2017/745. Quality assurance of the product is performed in accordance with the requirements of the international standard ISO 13485:2016, "Medical devices - Quality management systems - Requirements for regulatory purposes".



Henrik Wahlgren

QA Manager

Red colour of this
dot indicates
exposure to
irradiation