Vitrolife

Product:	**EmbryoSlide+™ ic8 dish**
Catalogue No.:	16454
Lot No.:	I-P8-2210-1
Manufactured:	October 2022

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".

Torben Christian Christensen

QC&RA Manager

Red color indicating exposure for radiation is indicated on CoA for ref. 16455. There is no differences in Design, Safety and efficacy between Ref 16454 and 16455

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Product:	**EmbryoSlide+™ ic8 dish**
Catalogue No.:	16455
Lot No.:	I-P8-2210-1
Manufactured:	October 2022
Expiry date:	2026-10-01

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.
Endotoxicity	This LOT is certified and documented with an endotoxin level of less than 20 EU/device as stated in the USP <85>.
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.

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" and in compliance with FDA CFR 21 Part 820.

Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner of its use.

Torben Christian Christensen
QC&RA Manager

Red colour of this dot indicates exposure to irradiation

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