

VitriMed

med.techn. Abt. der / medical department of

Mobil-Tec Elektronik GmbH

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CERTIFICATE OF BATCH ANALYSIS

As manufacturer and designer we confirm under sole responsibility herewith, that the following medical devices with the intended use for the cryopreservation of oocytes, embryos and sperms

“ VitriSafe ” Art.Nr.: **VIT-S-60, VIT-S-300, VIT-SC-50**

LOT # 114 (DOM 8/2019, DOE 8/2024)

have been inspected and tested during manufacturing and before final release in accordance to relevant specifications and requirements:

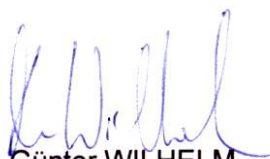
Test Description	Requirements	Result
Raw material	Certified by supplier	Complies
Visual inspection after moulding and before packaging	According to specification	Complies
Test of function	According to specification	Complies
Mouse Embryo Assay one cell, MEA	Blastocyst development > 80 %	Complies
Package and weld test	According to specification	Complies
Marking and Labelling	According to specification	Complies
Manual	Included	Complies
Sterility	According to specification	Complies *)

*) Sterility is obtained through irradiation > 25kGy according to ISO 11137 "Sterilization of health care products - Radiation" and in accordance with ISO 9001:2008 and ISO 13485:2003 "Medical devices – Quality management.

The product is CE marked according to EU directive, 93/42/EC for Medical device.

The products have been released on: 20.08.2019

Salzburg, 2019 08 25


Dr. Günter WILHELM CEO
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