Summary of Safety and Clinical Performance

Vitrification and Thawing Media

The purpose of this Summary of Safety and Clinical Performance (SSCP) is to offer public access to an updated summary of the main issues concerning the safety and clinical performance of the device. This document does not replace the Instructions for Use (IFU), which is the main document to ensure the safety of the device, and neither is it intended to provide advice on the diagnostic or therapeutic suggestions to the intended users.

0 Abbreviations

ART Assisted Reproductive Technologies
CPA Cryoprotectant Agents
EDQM European Directorate for the Quality of Medicines & HealthCare
EMA European Medicine Agency
EMDN European Medical Device Nomenclature.
ESHRE European Society of Human Reproduction and Embryology
EU European Union
DKMA Danish Medicines Agency
FSCA Field Safety Corrective Action
FSN Field Safety Notice
GSPRs General Safety and Performance Requirements
ICSI Intra Cytoplasmatic Sperm Injection
IFU instructions for use
IVF In vitro fertilization procedures
KPI Key Performance Indicator
MII Metaphase II
MDR Medical Device Regulation
MHRA Medicines and Healthcare products Regulatory Agency
NB notified body
PMCF post-market clinical follow-up
SRN single registration number for an economic operator
SSCP summary of safety and clinical performance
UDI-DI Unique Device Identification - Device Identifier

1 Device identification and general information

1.1 Device trade name(s)

- Kitazato Vitrification and Thawing Media without gentamicin: VT801/VT802.
- Kitazato Vitrification and Thawing Media with gentamicin: VT601/VT602 and VT601N/VT602N, VT601-BS1.5x4, VT601-ES1.5x4, VT601-VS1.5x4, VT601-BS4x4, VT601-ES4x4, VT601-VS4x4, VT602-TS4x4, VT602-DS4x4, VT602-WS4x4.
- Kitazato Ultra-Fast Vitri and Ultra-Fast Warm: VT601UF, VT601UF-4, VT601UF-ES x 4, VT601UF-VS x 4, VT601UF-ES4x4, VT601UF-VS4x4, VT602UF-TSx4.

1.2 Manufacturer's name and address

Kitazato Corporation

Address: 100-10 Yanagishima, Fuji, Shizuoka 416-0932 Japan
Phone: +81-545-65-7122 Fax: +81-545-65-7128
E-mail: ce_registration@kitazato.co.jp

1.3 Manufacturer's single registration number (SRN)

Kitazato Corporation SRN JP-MF-000018374

1.4 Basic UDI-DI

458223146VTUN

1.5 Medical device nomenclature description/text

Applicable EMDN code: U08020501: Materials/Solutions for Freezing/Thawing For Assisted Reproduction
Applicable MDR Code: MDN1212: Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)

1.6 Class of device

Vitrification and Thawing Media are considered medical devices Class III according to MDR (Regulation (EU) 2017/745) Annex VIII.

1.7 Year when the first certificate (CE) was issued covering the device

Kitazato Vitrification and Thawing Media without gentamicin (VT801/VT802, class IIb under Medical Device Directive 93/42/EEC Annex II): CE 563699, First issued 13/07/2012.

Kitazato Vitrification and Thawing Media with gentamicin (VT601/VT602 and VT601N/VT602N, class III under Medical Device Directive 93/42/EEC Annex II): CE 563702, First issued 05/09/2019.

All the above-mentioned variants obtained the CE mark under Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) (All variants are classified as Class III devices under MDR 2017/745, Annex IX Chapter II): MDR 760355 and MDR 760770, First issued 27/06/2024.

Ultra-Fast Warm (Class III under Medical Device Regulation (MDR) 2017/745, Annex IX Chapter II): MDR 760770, First issued 05/08/2024.

Ultra-Fast Vitri (Class III under Medical Device Regulation (MDR) 2017/745, Annex IX Chapter II): MDR 760770, First issued 10/04/2025.

1.8 Authorized representative; name and the SRN

Biomedical Supply, S.L. (Dibimed)
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SRN: ES-AR-000014358

1.9 Notified Body (NB)'s name and single identification number

British Standards Institution (BSI) Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

NB identification number: 2797

2 Intended use of the device

2.1 Intended purpose

- Vitrification Media are used for vitrification of oocytes [Metaphase II (MII)] and embryos.
- Thawing Media and Ultra-Fast Warm are used for thawing vitrified oocytes (MII) and embryos.
- Ultra-Fast Vitri is used for vitrification of oocytes (MII).

2.2 Indication(s) and intended patient groups

The media are indicated for vitrification and thawing of oocytes (MII) and/or embryos.

The target population are patients undergoing Assisted Reproductive Technologies (ART) procedures, which are typically indicated as treatments for patients with infertility problems.

2.3 Contraindications and/or limitations

Vitrification and Thawing media (VT60X variants) contain the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

3 Device description

3.1 Description of the device

The devices described in this Summary of Safety and Clinical Performance (SSCP) belong to the Kitazato Vitrification and Thawing Media family, designed to enable:

- Vitrification Media: vitrification of oocytes (MII) and embryos.
- Thawing Media and Ultra-Fast Warm: thawing of vitrified oocytes (MII) and embryos.
- Ultra-Fast Vitri: vitrification of oocytes (MII).

Therefore, this device family is designed to cryopreserve oocytes and/or embryos for Assisted Reproductive Technologies (ART) procedures.

Vitrification Media and Ultra-Fast Vitri contain cryoprotectant agents (CPAs) that permeate oocytes and embryos to prepare them for cryopreservation in liquid nitrogen. This process, known as vitrification, solidifies the cells without forming ice crystals, thereby preserving their structural integrity. Thawing Media and Ultra-Fast Warm are used to safely thaw and rehydrate the cryopreserved oocytes and embryos by gradually removing the cryoprotectants while minimizing osmotic shock.

Direct physical contact occurs between the vitrification and thawing media and oocytes and/or embryos. There is no direct contact between the device and the uterus mucosal membranes of the patient.

The Vitrification and Thawing Media family comprises the following variants:

With phenol red:
- VT801/VT802 (without gentamicin)
- VT601/VT602 / VT601UF/VT602UF (with gentamicin)

Without phenol red:
- VT601N/VT602N (with gentamicin)

The VT60X variants contain gentamicin, an antibiotic that helps suppress bacterial growth in the event of contamination during the use of vitrification and thawing media. This is the only difference between VT60X and VT80X variants. The added gentamicin complies with Ph. Eur. Monograph Standard 0331, and it is EDQM-certified. The inclusion of gentamicin in VT60X media has been accepted by the Danish Medicines Agency (DKMA). All variants contain phenol red as pH color-indicator except for VT60XN devices.

Vitrification Media is composed of BS, ES and VS Solutions (VT601/VT801/VT601N). On the other hand, Thawing Media is composed of TS, DS and WS Solutions (VT602/VT802/VT602N). Around 2023, a novel procedure to vitrify oocytes and warm vitrified oocytes/embryos was developed: the Ultra-Fast Vitri and Ultra-Fast Warm protocols. The Ultra-Fast Vitri procedure (VT601UF variants) only uses ES and VS Solutions for oocyte vitrification. Likewise, the Ultra-Fast Warm procedure (VT602UF variant) consists only of placing oocytes/embryos in TS Solution for 1 min at 37ºC. These protocols gave comparable survival rates, embryology, and reproductive outcomes to those obtained for the standard stepwise procedures, but have the advantage of decreasing time, ease the operability of the protocol, shortening the time of the embryos staying out of the incubators and reducing micromanipulation of oocytes/embryos.

Vitrification and Thawing media can be safely used up to one week after first opening when aseptic techniques are followed and the devices are stored as indicated (2-8ºC).

Vitrification and Thawing media are sterilized using aseptic processing techniques (filtration).

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

No previous generation of the devices have been brought on the market by Kitazato Corporation.

3.3 Description of any accessories which are intended to be used in combination with the device

No accessories for Kitazato Vitrification and Thawing media are identified.

3.4 Description of any other devices and products which are intended to be used in combination with the device

No specific devices and products to be used in combination with Vitrification and Thawing media are identified.

4 Risks and warnings

4.1 Residual risks and undesirable effects

No known undesirable side-effects are identified.

Benefit–risk statement: Based on the analysis of the collected clinical and post-market data, it is concluded that the benefit–risk profile of the device(s) remains unchanged and clearly favourable.

All identified risks are controlled and acceptable when weighed against the intended benefits to the patient. All identified risks were reduced to meet the pre-established acceptable levels by implementing the appropriate risk control measures and were acceptable when weighed against the benefits to the patient.

4.2 Warnings and precautions

Besides the above, attention should be paid to the following warnings and precautions (as described in the instructions for use):

Warnings	Precautions
• Read the instructions for use prior to use. • Use Kitazato Thawing Media to thaw the oocytes (MII) or embryos vitrified with Kitazato Vitrification Media (applicable to Vitrification Media IFUs). • Use Kitazato Thawing Media to thaw oocytes (MII) vitrified with Kitazato Ultra-Fast Vitri (applicable to Ultra-Fast Vitri IFUs). • This product is intended to be used by medical specialists trained in fertility treatment. • Aseptic technique should be used. • Use sterilized equipment and materials only. • In case of eye or skin contact with Vitrification/Thawing/Ultra-Fast Warm/Ultra-Fast Vitri media, immediately flush eye/skin with water. • Morphologically abnormal oocytes, embryos, or significantly poor grade oocytes or embryos are unsuitable for cryopreservation (applicable to Vitrification Media IFUs). • Morphologically abnormal oocytes or significantly poor grade oocytes are unsuitable for cryopreservation (applicable to Ultra-Fast Vitri IFUs).	• Don't re-sterilize. • Don't use solutions that show cloudiness or become discolored. • Don't use the product if you notice anything unusual regarding the specifications on the label (number, color, name, volume). • Device is sterilized if the vial is unopened or undamaged. • Don't use it if the package or container are opened or damaged. • Upon delivery media must be stored in original unopened container and refrigerated at 2-8 ºC. • Don't use and discard if the media is not stored under refrigeration (2 to 8 ºC). • Don't use the product after expiration date. Any serious incident (as defined in European Medical Device Regulation, 2017/745) that has occurred should be reported to Kitazato Corporation and, if applicable, the competent authority of the EU Member State in which the user and/or patient is established.

• Observe all federal, state, and local environmental regulations when discarding the product. • In case of contamination, dispose the product appropriately in a prescribed manner. • The user is responsible for any problems caused by incorrect use or not following the present IFU.	

4.3 Summary of any field safety corrective action (FSCA including FSN)

No field safety corrective actions (FSCA) or field safety notices (FSN) have been issued for Vitrification and Thawing Media devices.

5 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to similar/equivalent devices

The clinical evaluation of the device is not based on equivalence. Accordingly, no equivalent devices have been identified, and no clinical data related to equivalent or similar devices have been collected, as this section is not applicable. Kitazato has generated and documented sufficient clinical data from its own device to demonstrate compliance with the General Safety and Performance Requirements (GSPRs), and to support the safety and performance of the device.

5.2 Summary of clinical data from literature

The Alpha consensus meeting report published in 2012 presents the outcomes from an international workshop designed to establish consensus on definitions for key performance indicators (KPIs) for oocyte and embryo cryopreservation; minimum performance level values for each KPI, representing basic competency; and aspirational benchmark values for each KPI. The meeting included expert professionals from Turkey, UK, Australia, Italy, Spain, Germany, Austria, Canada, USA, and Belgium. As a starting point for the discussion, an interactive questionnaire was organized to collect information on indicators used in In Vitro Fertilization (IVF) laboratories worldwide. During the meeting, the results of the surveys, scientific evidence (where available), and personal clinical experience were integrated into presentations by experts on specific topics. After presentation, each proposed indicator was discussed until consensus was reached within the panel (Alpha Scientists in Reproductive Medicine, 2012).

The following minimal competency limits concerning laboratory/embryology outcomes were reported by the expert group and were considered as benchmark endpoints in the clinical evaluation of Kitazato Vitrification and Thawing Media devices:

- Survival rate oocytes: **≥70%**
- Survival rate cleavage stage embryos: **≥70%**
- Survival rate blastocysts: **≥80%**

Moreover, the ESHRE publishes a peer-reviewed report each year which collects and analyses ART data generated in Europe. The most recent report includes data from 1,487 institutions in 40 countries, with a total of 1,077,813 treatment cycles (covering the period from 1 January to 31 December 2019) (Smeenk et al. 2023) and it is summarized in the table below:

From 427,980 cycles performed using Intra Cytoplasmatic Sperm Injection (ICSI):

- Clinical pregnancy rate per aspiration: 26.2% (Range: 16.3 – 46.8%)
- Clinical pregnancy rate per transfer: 33.5% (Range: 26.9 – 52.1%)
- Delivery rate per aspiration: 18.8% (Range: 11.6- 35.9%)

- Delivery rate per transfer: 24.1% (Range: 12.1– 39.4%)

From 160,782 cycles performed using conventional IVF:
- Clinical pregnancy rate per aspiration: 28.5% (Range: 19.9 – 58.1%)
- Clinical pregnancy rate per transfer: 34.6% (Range: 27.4 – 63%)
- Delivery rate per aspiration: 20.9% (Range: 13.9- 48.8%)
- Delivery rate per transfer: 25.3% (Range: 17.9 – 43.5%)

From 335,744 frozen embryo transfer cycles:
- Pregnancy rate per thawing: 35.1% (Range: 22.5 – 50.1%)
- Pregnancy rate per transfer: 35.8% (Range: 22.5 – 56.0%)
- Delivery rate per thawing: 25.0% (Range: 7.2 – 42.4%)
- Delivery rate per transfer: 25.6% (Range: 8.4- 42.4%)

As there are no alternative treatment options that can be used for oocyte/embryo vitrification/thawing during IVF/ART procedures, all data included in the ESHRE report are generated using Kitazato Vitrification and Thawing Media or similar devices available on the market. Reported outcomes in the benchmark paper can therefore be considered as benchmark data for ART procedures. Nevertheless, when comparing clinical data, one should be aware that:

- ✓ During ART processes, oocytes/embryos come into contact with several (other) ART media and undergo a lot of manipulations that all can have an influence on the reported outcomes.
- ✓ Depending on the patient characteristics, different outcomes can be obtained.

A literature search is performed annually to investigate whether laboratory/embryology and/or clinical ART outcomes obtained from the use of Kitazato Vitrification and Thawing Media are consistent with the laboratory/embryology KPIs competency limits and/or with the clinical ART outcomes described in the benchmark papers from the ESHRE.

A total of 132 articles were retrieved to support the efficacy, clinical performance and safety profile of Kitazato Vitrification and Thawing Media devices. All articles reporting laboratory/embryology or clinical outcomes related to the use of Kitazato devices were consistent with the KPIs and ESHRE reference values established as endpoints, thereby supporting the safety and performance of the device for oocyte and embryo (cleavage, blastocysts and biopsied embryos) cryopreservation. The retrieved articles also supported the effective and safe performance of the devices for long-term cryopreservation and reported comparable laboratory/embryology and reproductive outcomes between conventional and ultra-fast procedures.

Moreover, none of the retrieved articles reported toxicity of the media for oocytes and/or embryos or any risk for cytotoxicity, allergenicity, irritancy, mutagenity, carcinogenity, oncogenicity or teratogenity for patients and users, demonstrating the safety of the device. Thus, from the literature data it could be concluded that the devices comprising Kitazato Vitrification and Thawing Media family are not detrimental for fertilization and embryo development, and do not interfere with the general ART procedure

Scientific articles describing the use of Kitazato Vitrification and Thawing Media devices are listed in Section 11 ‘References’ below.

5.3 Summary of real-world clinical data from IVF clinics

In addition to the above, clinical data was obtained from multiple IVF centers worldwide that use Kitazato Vitrification and Thawing Media devices for cryopreservation of oocytes and embryos following the traditional procedure, the drop protocol using standard dishes and/or the ultra-fast vitri/warm

procedures. The ART outcomes of these clinics were consistent with laboratory/embryology KPIs and with clinical outcomes described in the benchmark reports from the ESHRE, thereby supporting the safety and performance of Kitazato Vitrification and Thawing Media family.

5.4 Vigilance analysis and customer/market feedback

The clinical evaluation also included data from the state-of-the-art and verification and validation testing, device registries, vigilance activities and client feedback and complaints of Kitazato Vitrification and Thawing Media devices. No emerging risks, systematic missuse, previously unknown side effects / contra-indications were identified. Additionally, there were no incidents and/or field safety corrective actions taken related to the clinical and safe use of the device. Based on the analysis of the collected data, it is concluded that the benefit–risk profile of the device(s) remains unchanged.

5.5 An overall summary of clinical performance and safety

Vitrification and Thawing Media must effectively cryopreserve oocytes (MII) and embryos in a non-toxic, pathogen-free environment. Given the high sensitivity of oocytes and embryos to even minimal changes in their surrounding medium, the success of ART procedures can be significantly compromised by ice crystal formation, inadequate cryoprotectant concentrations, or low cooling and warming rates — all of which can lead to cell damage or destruction during cryopreservation. Therefore, Vitrification and Thawing Media devices must provide optimal physicochemical conditions that enable efficient water–cryoprotectant exchange, while maintaining the integrity of the cell membrane. This is essential to avoid adverse effects on fertilization and embryo development.

According to the information from the clinical evaluation report, it can be concluded that Vitrification and Thawing media function as stated by the manufacturer and can be safely and effectively used for cryopreservation of oocytes and embryos without leading to a detrimental effect on ART outcomes. Furthermore, the literature search and clinical data collected from IVF Clinics using Kitazato Vitrification and Thawing Media devices demonstrate their performance and safety, since the obtained outcomes are consistent with competency limits reported by ESHRE (Alpha Scientists in Reproductive Medicine, 2012; Smeenk et al. 2023); and no complications or problems were detected.

Kitazato Corporation has taken all necessary steps to ensure that residual risks associated with the use of Vitrification and Thawing Media are reduced as far as possible through application of existing state of the art techniques in the design and manufacture of these medical devices. Kitazato Corporation concludes that the overall medical benefits of Vitrification and Thawing Media outweigh the possible risks when used according to the intended use.

There is sufficient evidence to establish the safety and performance of Vitrification and Thawing Media when used in accordance with the IFUs. The clinical evaluation demonstrates that the available clinical data are sufficient to establish conformity with all applicable General Safety and Performance Requirements (Annex I) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and confirm the safety and performance of these devices. The Instructions for Use (IFU) clearly demonstrates safe usage of the device and mandatory physician training ensures all users are fully conversant with all aspects of device use. Kitazato Vitrification and Thawing Media have been confirmed to be within the current state-of-the-art practice.

5.6 Ongoing or planned post-market clinical follow-up

On a yearly basis, Kitazato Corporation will perform literature searches for Vitrification and Thawing Media as well as for gentamicin. Additionally, clinical data retrieved from IVF centers using Vitrification and Thawing Media devices will be evaluated.

This Summary of Safety and Clinical Performance will be updated with data from the post-market clinical follow-up (PMCF) if required, to guarantee that any clinical and/or safety information described in this summary stays right and complete.

6 Possible diagnostic or therapeutic alternatives

Currently, vitrification is the gold standard for cryopreserving oocytes and embryos in assisted reproduction. While slow-freezing was the original method—still used effectively for sperm preservation—it proved suboptimal for oocytes and embryos due to their lower survival rates after thawing. Vitrification prevents ice crystal formation and has significantly improved cell survival and clinical outcomes. Over time, advancements in vitrification protocols have made it essential in IVF, enabling treatments such as fertility preservation, egg accumulation for poor responders, and egg banking. Besides Kitazato Vitrification and Thawing Media devices or similar media, there are no alternatives for oocyte (MII) and embryo vitrification and thawing during ART procedures.

7 Suggested profile and training for users

Vitrification and Thawing media are intended to be used by medical specialist trained in fertility treatment (laboratory technicians, embryologists, or medical doctors). Vitrification and Thawing media are used in specialized laboratories performing fertilization techniques, including IVF, ICSI and sperm preparation/ analysis.

8 Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)

The following guidance documents were used:

- MDCG 2019-09: Summary of safety and clinical performance. A guide for manufacturers and notified bodies (Rev.1 (March 2022) (fully applicable)
- ISO 13408-1:2023 / EN ISO 13408-1:2024: Aseptic processing of health care products – Part 1: general requirements (fully applicable).
- (EN) ISO 13408-2:2018: Aseptic processing of health care products – Part 2: Filtration (full applicable).
- (EN) ISO 13408-6:2021: Aseptic processing of health care products – Part 6: Isolator systems (fully applicable).
- ISO 13485:2016 / EN ISO13485:2016/Amd 11:2021: Medical devices — Quality management systems — Requirements for regulatory purposes (fully applicable).
- MDR 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (fully applicable).
- ISO 10993-1:2018 / EN ISO 10993-1:2020 + A11:2021: Biological evaluation of medical devices -- Part 1: Evaluation and testing (fully applicable).
- (EN) ISO 10993-3:2014: Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (fully applicable).
- EN ISO 10993-5:2009/A11:2025: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity (fully applicable).
- (EN) ISO 10993-10:2023: Biological evaluation of medical devices - Part 10: Tests for skin sensitization (fully applicable).
- (EN) ISO 10993-12:2021: Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (fully applicable).
- ISO 10993-15:2019 / EN ISO 10993-15:2023: Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (fully applicable).
- ISO 10993-18:2020/Amd 1/2022 / EN ISO 10993-18:2020/A1:2023: Biological evaluation of

medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (fully applicable).

- (EN) ISO 10993-23:2021: Biological evaluation of medical devices – Part 23: Tests for irritation (fully applicable).
- EN 556-2:2024: Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' –Requirements for aseptically processed medical devices (fully applicable).
- (EN) ISO 20417:2021: Medical Devices: information supplied by the manufacturer (fully applicable)
- (EN) ISO11737-1:2018/A1:2021: Sterilization of health care products- Microbiological methods Part 1: Determination of a population of microorganism on products (fully applicable).
- ISO 11737-2:2019 / EN ISO 11737-2:2020 Sterilization of health care products- Microbiological methods Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process (fully applicable).
- (EN) ISO 14644-1:2015: Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration (fully applicable).
- (EN) ISO 14644-3:2019: Cleanrooms and associated controlled environments - Part 3: Test methods (fully applicable).
- ISO 14971:2019 / EN ISO 14971:2019/Amd 11:2021: Medical devices – Application of risk management to medical devices (fully applicable).
- ISO 15223-1:2021/A1:2025: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (fully applicable).
- (EN) ISO 17665:2024: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (fully applicable).
- ISO 23640:2011/ EN ISO 23640:2015: In vitro diagnostic medical devices: Evaluation of stability of in vitro diagnostic reagents. Applicable with exclusion of the following sections: No standard is available for the evaluation of stability of Medical Devices, therefore this standard is used as guideline for the set-up of the stability testing in line with the EU list of harmonized standards drafted in support of Council Directive 93/42/EEC and MDR 2017/745.
- (EN) ISO 22442-1: 2020: Medical Devices utilizing animal tissues and their derivatives: Part 1: Application of risk management (fully applicable).
- EN 17141:2020 Cleanrooms and associated controlled environments - Biocontamination control (fully applicable).
- European Pharmacopeia, (2.6.14) Bacterial Endotoxin - Turbidimetric Kinetic Method (fully applicable).
- European Pharmacopeia, (2.2.3) pH Test (fully applicable).
- European Pharmacopeia, (2.2.35) Osmolality (fully applicable).
- European Pharmacopeia, (3.2.2) Plastic Containers and closures for pharmaceutical use (fully applicable).
- European Pharmacopeia, (3.1) Poly (Ethylene - Vinyl Acetate) for containers and tubing for total parenteral nutrition preparations. Applicable with exclusion of the following sections: (3.1.7).
- IEC 62366-1:2015/A1:2020: Medical devices - Part 1: Application of usability engineering to medical devices (fully applicable).
- EN ISO 2859-1:2012 / ISO 2859-1:1999/Amd 1:2011: Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (fully applicable).

- (EN) ISO 14644-5:2025 Cleanrooms and associated controlled environments – Part 5: Operations (fully applicable).
- ASTM D-4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems (fully applicable).
- NBOG BPG 2014-3: Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System (fully applicable).
- EMA/CHMP/578661/2010 rev.1: EMA recommendation on the procedural aspects and dossier requirements for the consultation to the EMA by a notified body on an ancillary medicinal substance or an ancillary human blood derivate incorporated in a medical device or active implantable medical device (fully applicable).
- MHRA guidance note 31 (updated 2017): Guidance for notified Bodies: Devices which incorporate an ancillary medicinal substance (fully applicable).
- USP38-NF33 <88> Biological Reactivity Tests – United States Pharmacopia, Inc <88> Biological Reactivity Tests, in vitro. Intracutaneous Test. Official August Date 01, 2015 (fully applicable).
- ASTM D-4169-23e1 Standard Practice for Performance Testing of Shipping Containers and Systems (fully applicable).
- EP (2.6.1) Sterility Test European Pharmacopeia (2.6.1) Sterility (fully applicable)
- MEDDEV 2.7/1 rev.4 (4 June 2016) Clinical evaluation: Guide for manufacturers and notified bodies
- MEDDEV 2.12/1 rev.8 Guidelines on a Medical Devices Vigilance System.

9 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2022/06/21	Initial version	Date: not yet Validation language: English
2	2023/11/16	Updated as per BSI review	Date: not yet Validation language: English
3	2023/12/12	Inclusion of new variants	Date: 02/02/2024 Validation language: English
4	2024/04/17	Updated device registries and product references	Date: 18/06/2024 Validation language: English
5	2024/09/20	Updated device registries and product references	Date: not yet Validation language: English
6	2025/01/24	Updated intended use	This version has been validated by the Notified Body. Date: 17/02/2025 Validation language: English
7	2025/09/08	Annual update	This version has been validated by the Notified Body. Date: 07/11/2025 Validation language: English

10 Summary of the safety and clinical performance for patients

As the device is for professional use only, a summary of the safety and clinical performance of the device intended for patients is not applicable.

11 References

1. Alpha Scientists In Reproductive Medicine. The Alpha consensus meeting on cryopreservation key performance indicators and benchmarks: proceedings of an expert meeting. Reprod Biomed Online. 2012 Aug;25(2):146-67. doi: 10.1016/j.rbmo.2012.05.006.
2. Alteri A, Reschini M, Guarneri C, et al. The effect of laser-assisted hatching on vitrified/warmed blastocysts: the ALADDIN randomized controlled trial. Fertil Steril. 2024 Jul;122(1):106-113. doi: 10.1016/j.fertnstert.2024.02.010.
3. Amagai A, Ezoe K, Miki T, Shimazaki K, et al. Fatty acid supplementation into warming solutions improves pregnancy outcomes after single vitrified-warmed cleavage stage embryo transfers. Reprod Med Biol. 2023 May 8;22(1):e12517. doi: 10.1002/rmb2.12517.
4. Arnanz A, De Munck N, Bayram A, et al. Blastocyst mitochondrial DNA (mtDNA) is not affected by oocyte vitrification: a sibling oocyte study. J Assist Reprod Genet. 2020 Jun;37(6):1387-1397. doi: 10.1007/s10815-020-01795-6.
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6. Aydin B, Hudkova D, Maggiotto G, et. al. O-294 Human oocyte survival, early embryo development, metabolic fingerprinting, and pregnancy outcomes following ultra-rapid or standard vitrification and thawing. Human Reproduction, Volume 39, Issue Supplement_1, July 2024, deae108.351, https://doi.org/10.1093/humrep/deae108.351.
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