KITAZATO®

EC DECLARATION OF CONFORMITY

Manufacturer:		**Kitazato Corporation** **Shizuoka Office** **Address: 81 Nakajima, Fuji, Shizuoka 416-0907 Japan** **Phone: (+81) 545 66 2202 Fax: (+81) 545 60 5772** **E-mail: info@kitazato.co.jp**
European Representative:		**Dibimed-Biomedical Supply, S.L.** **Address: C/Luis Buñuel, 1 – Oficinas Puerta4, 46015 Valencia, Spain** **Phone: (+34) 963 056 395 Fax: (+34) 963 056 396** **E-mail : info@dibimed.com**
Product:	**Trade Name:**	**Cryotop**
	Code number:	**Cryotop® (G) Ref: 81111 / Cryotop® (R) Ref: 81112** **Cryotop® (W) Ref: 81113 / Cryotop® (B) Ref: 81114** **Cryotop® (Y) Ref: 81115** **Cryotop®SC (G) Ref: 81121 / Cryotop®SC (R) Ref: 81122** **Cryotop®SC (W) Ref: 81123 / Cryotop®SC (B) Ref: 81124** **Cryotop®SC (Y) Ref: 81125**
	Description:	**A PET-film attached to ABS-handle and equipped with a straw cap, used to load and store oocytes or embryos in vitrification and for preservation.**
	Classification:	**Class II a** **Rule 2 according to Annex IX of the MDD**
Conformity Assessment Route:		**Annex V applied**

We hereby declare that the above-mentioned devices comply with the (legislation of the member states where the Notified Body is located - if a Notified Body is involved -) transposing European Medical Devices Directive 93/42/EEC.
Kitazato Corporation is solely responsible for this Declaration of Conformity.

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), as amended by Directive 2007/47/EC.

Standards: Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are as per the "LIST OF APPLIED STANDARDS".

Notified Body: BSI (ID #: 2797)
British Standards Institution Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Tel: +31 20 346 0780

EC Certificate: Standard: EN ISO 13485:2016
EC Certificate #: 548538
Issued by: BSI PRODUCT SERVICES

Signature: _____ Date: 26 Feb 2021

Name: Futoshi INOUE
Position: President and Representative Director, Kitazato Corporation