

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 563702**  
**Issued To:** **Kitazato Corporation**  
**Shizuoka Office**  
**81 Nakajima**  
**Fuji-city**  
**Shizuoka**  
**416-0907**  
**Japan**

In respect of:

**Sterile vitrification and thawing media with gentamicin sulfate for use in assisted reproductive processes.**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-09-05**

Date: **2019-09-05**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.



**ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN**  
*EMBASSY OF THE S.R. OF VIET NAM IN JAPAN*  
**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ**  
*CONSULAR AUTHENTICATION*

1. Quốc gia: VIỆT NAM  
*Country: Viet Nam*  
Giấy tờ, tài liệu này  
*This public document*
2. Do ông (bà): **TOSHIE TANAKA** ký  
*Has been signed by*
3. Với chức danh: **CÔNG CHỨC**  
*Acting in the capacity of OFFICIAL*
4. Và con dấu của: **BỘ NGOẠI GIAO NHẬT BẢN**  
*Bears the seal/stamp of: MINISTRY OF FOREIGN AFFAIRS OF JAPAN*

được chứng nhận/hợp pháp hóa lãnh sự  
*Certified*

5. Tại: Tô-ki-ô  
*At: Tokyo*
6. Ngày: 24/03/2020  
*The (dd/mm/yyyy)*
7. Cơ quan cấp: ĐÀI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN  
*By EMBASSY OF THE S.R. OF VIET NAM IN JAPAN*
8. Số: **24/03/20-021/HPHLS**  
*Nº*

TL. Đại sứ/For the Ambassador  
Bí thư thứ nhất/First Secretary



NGUYỄN AN TIẾN