
Certificate of Irradiation

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|-----------------------------|------------------------------------|------------------------|
| Product | Nunc Cell Factory Systems, 2 Trays | Date 2025-09-18 |
| | | Page 1 |
| Item Number | 167695 | |
| Lot Number | 187006 | |
| Specified Dose Range | 27.6 - 49.9 kGy | |
| SAL | 10E-6 | |
| Quantity | 64 boxes | |

Thermo Fisher Scientific confirms that the product supplied has been inspected and tested in accordance to relevant specifications.

| Irradiation lot no. | PalletID | Date of irradiation | Dose kGy |
|---------------------|------------|---------------------|----------|
| EC__1302619B | DK00411656 | 2025-09-02 | 34.4 |
| EC__1302605B | DK00411657 | 2025-09-02 | 35.2 |
| EC__1302689B | DK00411658 | 2025-09-02 | 34.8 |
| EC__1303844B | DK00411655 | 2025-09-02 | 34.4 |

Sterility is obtained through irradiation according to ISO 11137 "Sterilization of health care products - Radiation".

Quality assurance of the product is performed in accordance with the requirements of the Quality Management System ISO 9001:2015 "Quality Management System - Requirements" and ISO 13485:2016 "Medical Devices - Quality Management Systems - System requirements for regulatory purposes".

Roskilde Site



Per Bernack
Senior Quality Assurance Manager

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