
Certificate of Conformity

Product: Nunc 12 well Multidishes

Date: 2019-08-13

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Item number: 150628**Lot number:** 162259**Date of manufacture:** August 2019**Date of expiry:** August 2024

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

| Test Description | Requirements | Result |
|---|----------------------------|------------|
| Visual | According to specification | Complies |
| Test of function | According to specification | Complies |
| Cloning efficiency with V-79 cell line | According to specification | Complies* |
| USP <85> Bacterial endotoxins test | <0.5 endotoxins unit/ml | Complies* |
| USP <88> "Biological Reactivity test In Vivo, USP Class VI Test" | USP current edition | Complies** |
| Cell Culture Test L 929 Human Lung Primary chicken embryo | According to specification | Complies* |

*Performed as monitoring test

**Only performed once

Sterility is obtained through irradiation according to ISO 11137 "Sterilization of health care products - Radiation", with SAL 10E-3.

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

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