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## **Certificate of Conformity**

Product: Nunc Dish Nunclon 150 x 20 Date: 2019-05-10 Page: 1

Item number:168381Lot number:161485Date of manufacture:April 2019Date of expiry:April 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<br>In Vivo, USP Class VI Test" | USP current edition        | Complies** |
| Cell Culture Test L 929 Human Lung Primary chicken embryo           | According to specification | Complies*  |

<sup>\*</sup>Performed as monitoring test

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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Quality Systems, Support and Monitoring, Team Leader

<sup>\*\*</sup>Only performed once