

Thermo Fisher Scientific Nunc A/S Kamstrupvej 90, P.O.Box 280 DK-4000 Roskilde, Denmark +45 4631 2000 Tel Info.nunc@thermofisher.com A/S 24482 VAT/SE NO. DK 39582910 www.thermofisher.com

Date: 2019-10-17

1

Page:

Certificate of Conformity

Product: Nunc Dish Nunclon 100 x 20

Item number: 172931

Lot number: 162591

Date of manufacture: October 2019

Date of expiry: October 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 | According to specification | Complies* |

Primary chicken embryo

*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

Emil O'Hanlon Cohrt, PhD Quality Systems, Support and Monitoring, Team Leader