

### **Product statement**

**Products:** Nunclon Sphera  
**Raw materials:** Polystyrene, PS (65927)  
Caps for flasks:  
High Density Polyethylene HDPE (43847)  
Sartorius filter (35690)  
Blue masterbatch (48452)  
Hydrophilic polymer coated surface (low binding)

Thermo Fisher Scientific hereby confirms that the product above was produced, inspected and found to be in compliance with the following product and quality specifications.

#### **The products and the materials have successfully passed the following tests:**

- USP <87> "Biological Reactivity Tests, In Vitro, Elution test".
- USP <88> "Biological Reactivity tests, In Vivo", Class VI.

#### **Inspection point of the products:**

Visual control according to our quality inspection procedures and specifications.  
Test of function according to our quality inspection procedures and specifications.

#### **Protein Adsorption:**

Protein used Assay Peroxidase-conjugated IgG adsorption level less than 2.0%

#### **Cell Adhesion:**

Cell adhered rate level less than 1.0%, except for F96 well plate: Cell-adhered wells rate level less than 5.0%.

#### **USP <85> "Bacterial Endotoxins Test":**

Non-pyrogenic test is performed according to the principles of the LAL-test as stated in the USP <85> "Bacterial Endotoxins Test" and is certified non-pyrogenic. Documented endotoxin level is less than 0.5 Endotoxin Units/ml (20 Endotoxin Units/device).

#### **Sterility:**

Sterility is obtained by ethylene oxide gas according to ISO 11135-1 "Sterilization of health care products - Ethylene oxide", with SAL 10E-6.

The expiry date is manufacturing date plus 4 (four) years.

Quality assurance of the product is performed in accordance with the requirements of Quality Management System ISO 9001:2015 "Quality management system - Requirements".

Roskilde S

Signature:

Date: 2022-08-23  
(YYYY-MM-DD)