Thermo Fisher Scientific
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Product statement

Products: Nunc Inoculation Needle, Sterile

Raw material: Polystyrene (61662)
Yellow masterbatch (55808)

We hereby confirm that the above-mentioned products have been designed and are manufactured from selected material, polystyrene (PS) and Yellow masterbatch.

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.

The materials have successfully passed the following test:
USP <88> "Biological Reactivity Tests, In Vivo" class VI.

Sterility and Bioburden:
Sterility is obtained through irradiation (gamma irradiation) according to ISO 11137-2 (sterilization of health care products – requirements for validation and routine control – radiation sterilization). Consecutive audit of sterility is performed every 3 month.
Sequential inspection of the particle level is made in the production environment.

Sterility assurance level (SAL): 10^{-6}

Expiry is manufacturing plus 5 (five) years.

Quality assurance of the products are 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

Signature: Maria Elisa Rex
Maria Elisa Rex, QA Coordinator

Date: 2019-04-16
(YYYY-MM-DD)