

CERTIFICATE OF COMPLIANCEFILTER STERILE Part No. 153015

This is to certify that the materials used in the manufacture of the product meet the requirements for the United States Pharmacopeia USP Class VI Biosafe product. The product described below has been tested and released by INTEGRA Biosciences AG, 7205 Zizers, Switzerland based on the results of approved test methods. The quality management system under which it was manufactured is in compliance with ISO 9001.

Description:

Filter 0.45 µm sterile

Part Number:

153015

Lot Number:

452140

Date of sterilization:

2021-10

Shelf life of sterility:

3 years

Expiration date:

2024-09

Housing material:

PVC, outlet is blue

Connectors:

Male slip luer

Filter material:

PTFE

Pore size rating:

0.45 µm

Packaging:

Single blister, sterile

Sterilization method:

EO (Ethylene Oxide) according to ISO 11135-1

Sterilization Assurance Level (SAL) 10-6

BSE/TSE Declaration:

The filter product is produced with raw materials manufactured in conformity with the European Community Directive 2003/32/EC.

This certificate applies only to products in undamaged condition, which have been shipped, stored and / or used in appropriate manner.

INTEGRA Biosciences AG CH-7205 Zizers, Switzerland www.integra-biosciences.com

Thomas Tichy Quality Manager

2021-10-25