

Declaration of Conformity

INTEGRA

Product name: Filter sterile (0.20 µm) **Part number:** 156608

Lot number: 2020240521

Production date: 21.05.2024

Expiry date: 21.05.2027

Our commitment to customers:

INTEGRA sterile filters are produced from PVC using precise and consistent manufacturing techniques that ensure quality and excellent performance and have a PTFE filter material with a pore size of 0.2 µm. We strive to exceed our customers' expectations and encourage continuous feedback. The filters are manufactured in accordance to ISO 9001.

The product lots are traceable down to the corresponding raw materials used and date produced.

The manufacturing process incorporates consistent and continuous inspection throughout all phases of the manufacturing process. The sterile filters produced under these strict conditions are contaminant free and consistent from lot-to-lot.

Sterility: These products are sterilized in single blisters with ethylene oxide under controlled conditions and are considered sterile until opened. Sterile products have been released compliant with ISO 11135. The products meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

BSE-TSE statement: The raw material to produce the filter is conform with the European Community Directive 2003/32/EC.

Housing details: The raw material used to produce components is free of DEHP plasticizer, latex and conflict materials. The materials fulfil the standards of Reach 1907/2006/EC and RoHS 2011/65/EU. The connectors are male luer slips and the filter can be mounted in any direction.

Cytotoxicity testing: The testing is conducted to qualify that all materials use USP and/or ISO 10993 standards for cytotoxicity.

This certificate is valid for the above mentioned lot and has no validity if no lot number is provided.

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