

# Declaration of Conformity

# INTEGRA

**Product name:** Filter sterile (0.45 µm) **Part number:** 153015

**Lot number:** 4520240905

**Production date:** 2024.09.05

**Expiry date:** 2027.09.05

## 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 0.45 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 outlet side of the filter is blue. The connectors are male luer slips.

**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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