

INFORMATION FOR A TECHNICAL FILE

Product Number: MT 100
(Includes MT 100-TA and MT 100-A)

Product Name: FIO2 Sensor Activation System

FDA Certification: Approved as an accessory to 510(k) K973282

Product Number: MT 100-TA

Product Name: Replacement Tee

Product Description: 22mmOD X 22mmID

Engineering Drawing(s): Included

Material Specifications: Polypropylene
Huntsman H0500 Natural Translucent

Biological Toxicity Specifications: FDA 21 CFR 177.1520 c 1.1
USP Class VI
Approved in FDA 510(k) K963347

Color Dye Specification: Blue
Washington Penn Plastics SE-6488

Product Number: MT 100-A

Product Name: Replacement Activator

Engineering Drawing(s): Included

Material Specifications: Polycarbonate, High Heat
Bayer Lexan PPC 4707 Natural

Biological Toxicity Specifications: FDA compliant
Approved in FDA 510(k) K963347 and K973066

Color Dye Specification: Not Applicable