

TECHNICAL DATASHEET

Edition: Feb-20

FMA 798 N T01

MATERIAL TYPE:

Thermoplastic compound, vinyl based

Soft

APPLICATION*:

Medical Devices

TRANSFORMATION:

Injection Molding

REGULATORY & CERTIFICATIONS:

Do NOT contain any substance listed in the SVHC list (last update)

Do NOT contain any Phthalate relevant for MDD (>1.000ppm)

Do NOT contain any raw material of animal origin

USP class VI (last edition)

STERILIZATION SUGGESTED**:

EtO (Ethylene Oxide) or Irradiation

MATERIAL DETAILS:

Thermal Stabilization: Ca/Zn stearate complex

Softener: DEHT (Terephthalic acid bis(2-ethylhexyl)ester)

Ultramarine Pigments

TECHNICAL DETAILS

Specific Gravity

METHOD

ISO 1183-1

Unit

kg/dm³

VALUE

1,22±0,02

Hardness

ISO 868

Shore A 15" (24h)

79±2

Thermal Stability

ISO 182

sec

>1500

Cytotoxicity

ISO 10993-5

n/a

NOT Cytotoxic

Tensile strength at Break

ISO 527

Mpa

16 - 20

Elongation at Break

ISO 527

%

290 - 350

* Application is only an indication of potential use of the product. Verification of effectiveness of application is customer responsibility.

** If Applicable. Sterilization indicated is the method for which the material has been designed for. Other sterilization methods can be applied on exclusive responsibility of the customer.

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Customer is the sole responsible of final article immission on market.