

Material Code M0005

Revision 00

Type ABS
Brand name LUSTRAN 348
Supplier INEOS

Sterilization Stability:

| | <u>Compliant</u> | <u>Comments</u> |
|---------------------|------------------|-----------------|
| Gamma Sterilization | YES | Up to 60kGy |
| Ethylene Oxide | YES | - |

Biocompatibility Data:

| | <u>Compliant</u> | <u>Standard</u> | <u>Comments</u> |
|--------------|------------------|-----------------|--|
| USP Class VI | YES | - | meet the requirements of the FDA-Modified ISO 10993 matrix |

Main Regulatory Compliances:

| | <u>Compliant</u> | <u>Comments</u> |
|---|------------------|---------------------------------------|
| BPA | YES | Not used in the manufacturing process |
| Conflict Minerals | YES | Not used in the manufacturing process |
| Drug Master File | YES | - |
| Food Contact | YES | 21 CFR 181.32 |
| European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2 | YES | Not used in the manufacturing process |
| European Directive 2003/11/EC | YES | Not used in the manufacturing process |
| European Pharmacopoeia | YES | Chapter 3.2.2 |
| Latex or Natural Rubber | YES | Not used in the manufacturing process |
| Phthalates | YES | Not used in the manufacturing process |
| TSE / BSE | YES | Not used in the manufacturing process |
| US Pharmacopoeia | YES | US Pharmacopoeia 23 |
| European Directive (EC 1907/2006) REACH | YES | - |
| SVHC List | YES | Not used in the manufacturing process |
| MSDS | YES | - |

Technical Characteristics:

| | <u>Value</u> | <u>Measuring Method</u> | <u>Comments</u> |
|---------------------------------------|--------------|-------------------------|---|
| Injection | YES | - | - |
| Density | 1.06 g/cm3 | ASTM D 792 | - |
| Melt Flow Rate | 5 g/10min | ASTM D 1238 | MFR 230°C/3.8kg |
| Modulus of Elasticity / Young modulus | 2600 MPa | ASTM D 638 | - |
| Tensile Strength at Yield | 48 MPa | ASTM D 638 | - |
| Hardness | R 112 | ASTM D 785 | ROCKWELL |
| Impact strength | 214 J/m | ASTM D 256 | 0.125-in (3.2-mm) Thickness 73°F (23°C) |
| Other mechanical property 1 | 2700 MPa | ASTM D 790 | FLEXURAL MUDULUS |
| Other mechanical property 2 | 76 MPa | ASTM D 790 | FLEXURAL STRESS AT YIELD |

| | | | |
|---------------------------|----------|-------------------------|----------|
| R&D Validation | GVA | QA/RA Validation | ABA |
| Date | 10/05/17 | Date | 10/05/17 |

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promeppla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promeppla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.