

TECHNICAL DATA SHEET

UHMWPE Rod - Medical Grade

(Purity: 99.9%, Diameter: 50mm, Length: 500mm)

Stock No: NHS01-00007, CAS: 9002-88-4

| | | |
|-------------------|---|---|
| Product | : | UHMWPE Rod |
| Stock No | : | NHS01-00007 |
| CAS | : | 9002-88-4 |
| Purity | : | 99.9% |
| Grade | : | Medical |
| Diameter | : | 50mm |
| Length | : | 500mm |
| Molecular Formula | : | (CH ₂ C ₅₂) _n |
| Molecular weight | : | 4 million |
| Form | : | Solid |
| Colour | : | White |

| Material Properties | Specification | Standard | Units |
|---|-----------------------------|-----------------|----------------------|
| Average molecular weight | approx. 5 * 10 ⁶ | | g/mol |
| Elongation Stress F (150/10) | >0.2 | | (Mpa) |
| Viscosity number (VN) | > 2000 | | (ml/g) |
| Density | 927 – 944 | ISO 1183 | (kg/m ³) |
| Water absorption at 23° C until saturation | < 0,01 | ISO 62 | (%) |

| Mechanical Properties | Specification | Standard | Units |
|------------------------------|----------------------|-----------------|----------------------|
| Tensile stress at yield | > 21 | ISO 527 | (MPa) |
| Tensile stress at break | > 35 | ISO 527 | (MPa) |
| Elongation at break | > 300 | ISO 527 | (%) |
| Tensile modulus | approx. 720 | ISO 527 | (MPa) |
| Impact strength | no break | ISO 179 | (kJ/m ²) |
| Notched impact strength | > 180 | ISO 11542-2 | (kJ/m ²) |
| Ball indentation hardness | 30 – 35 | ISO 2039-1 | (N/mm ²) |
| Shore-Hardness D, 15 s value | 60 – 65 | ISO 868 | (-) |

| Thermal properties | Specification | Standard | Unit |
|--|----------------------|-----------------|--------------|
| Melting point DSC, 10 K/min | 130 – 135 | ISO 3146 | (°C) |
| Vicat softening point | 80 | ISO 306 | (°C) |
| Thermal expansion between 23 and 80° C | 2 * 10 ⁻⁴ | ISO 11359 | (K-1) |
| Heat deflection temperature | 42 | ISO 75, Teil | (°C) |
| Thermal conductivity | approx. 0,4 | ISO 52612 | (W/[m*K]) |

| Electrical properties | Specification | Standard | Unit |
|---------------------------------|------------------------|-----------------|-------------|
| Relative permittivity at 100 Hz | 2,1 | IEC 60250 | (-) |
| Dissipation factor at 100 Hz | 3,9 * 10 ⁻⁴ | IEC 60250 | (-) |
| Volume resistivity | > 10 ¹⁴ | IEC 60093 | (Ohm*m) |
| Surface resistivity | > 10 ¹³ | IEC 60093 | (Ohm) |
| Dielectric strength | 45 | IEC 60243 | (kV/mm) |

Physiological properties

Food conformances according to

| | Specification |
|------------------------------|----------------------|
| EU Directive 2002/72/EC | Yes |
| FDA Regulation 21CFR177.1520 | Yes |
| FDA Regulation 21CFR178.2010 | N/A |
| FDA Regulation 21CFR178.3297 | N/A |

Sterilisation

| | Specification |
|------------------------------|----------------------|
| Etyhlene oxide | Yes |
| Gas plasma | Yes |
| Gamma (inert atmosphere) | Yes |
| Superheated steam 121/134° C | No/No |

Conformances

| | Specification |
|--------------------------|----------------------|
| USP Class VI | Yes |
| Cytotoxicity | Yes |
| Drug Master File – DMF | 10916-EU |
| Drug Master File – DMF | 10904-USA |
| Device Master File – MAF | 588 |
| ISO 5834-2 | Type 1 |
| ASTM F 648 | Type 1 |

Main Inspect Verifier

Date of Print

Version

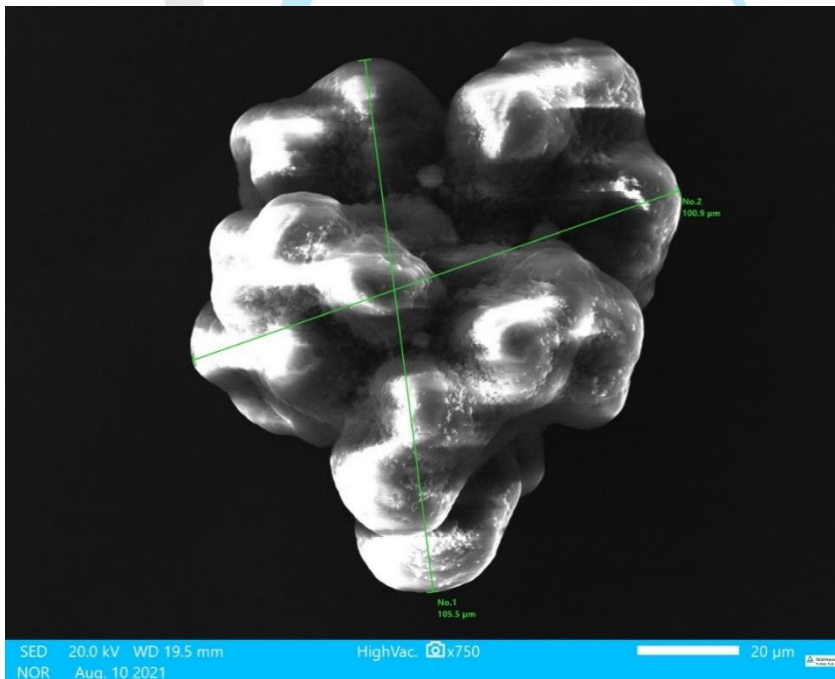
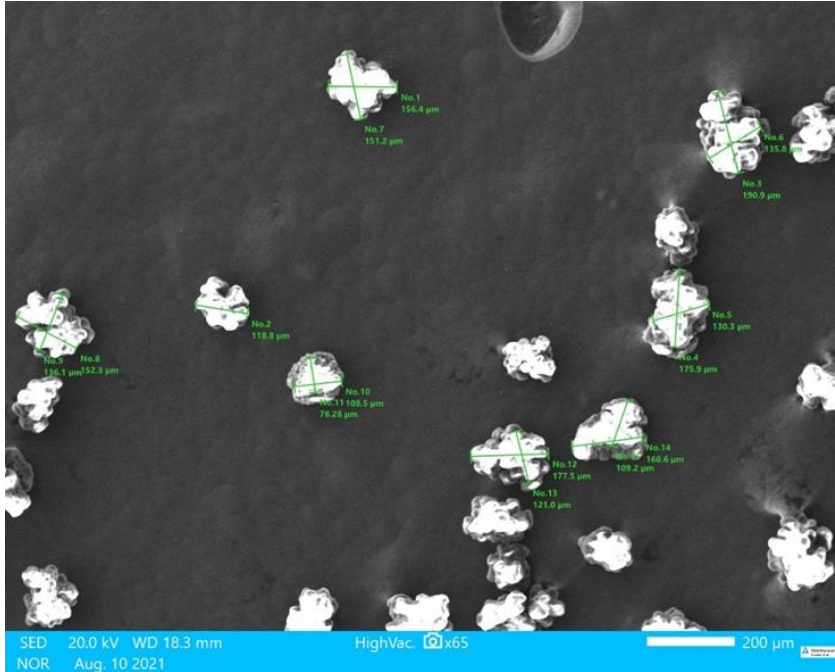
Manager QC

October 2021

1

Note: Product Specification are subject to amendment and may change over time

Scanning Electron Microscope (SEM) Analysis: Item: UHMWPE Powder



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Regd office: Plot #: 123, Industrial Area (Ph-2), Panchkula -134113 HR (INDIA)

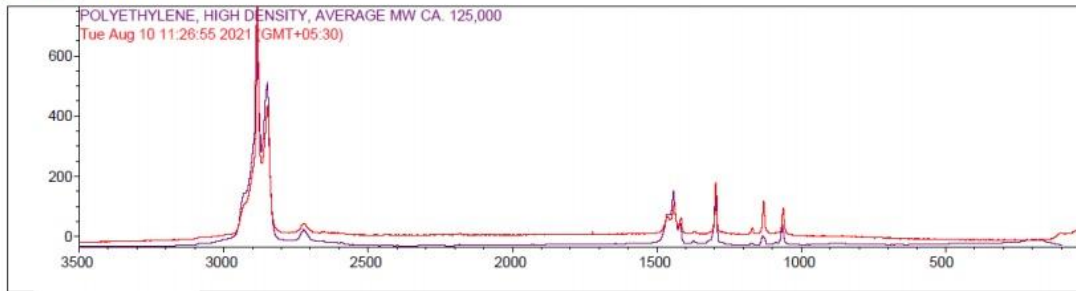
Tel: +91-9815 85 9815, 9815 50 9815 | ✉ sales@nanoshel.com, nanoshelhealthcare@gmail.com

RAMAN ANALYSIS OF UHMWPE

Item: UHMWPE Powder

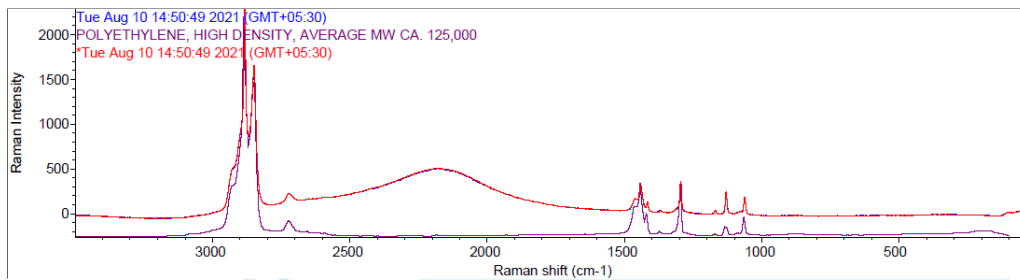
Raman Analysis:

Item: UHMWPE Powder



Result: The powder is identified as high density Polyethylene (HDPE)

Item: UHMWPE Extruded Bar



Result: The extruded bar is identified as high density Polyethylene (HDPE), with broadening observed between 2000-2400 cm-1.

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UHMWPE
— RODS —
Medical Grade

NANOSHEL HEALTHCARE PVT. LTD.

Manufacturing Unit:

I Hub B1, Ground Floor, Andhra Pradesh
Medtech Zone Ltd, Survey No 480/2, Nadupuru
Village Pedagantyada Mandal, Visakhapatnam,
Andhra Pradesh, 530031 (India)



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Nanoshel Healthcare Pvt. Ltd.

*Manufacturers of UHMWPE Rods and Medical Implants



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