

# Connecting You to Solutions for the **Healthcare Market**

We connect healthcare OEMs and processors  
with world-class quality products

## **We Tailor Customized Solutions to Help You:**

- Select the Right Material
- Improve Profitability
- Meet Safety and Compliance Requirements
- Ensure Supply Continuity
- Enjoy Best-in-Class Service
- Achieve Sustainability Goals

A hand in a white lab coat points towards a cluster of healthcare-related icons. The icons include a large blue hexagon with a white cross, a white hexagon with a blue pill, a blue hexagon with a white wheelchair, a white hexagon with a blue stethoscope, a blue hexagon with a white syringe, a white hexagon with a blue heart, and a blue hexagon with a white group of people. The background is a blurred image of a person's face.

**nexeo**<sup>®</sup>  
plastics

# Performance materials support a wide range of requirements

### IMPORTANT

Nexeo Plastics does not support certain healthcare applications, including Class III medical devices and implants. As such, all potential or known healthcare applications must be reviewed by Nexeo Plastics' personnel pursuant to Nexeo Plastics' Healthcare Applications Policies in advance. Nexeo Plastics' technical team is available to help you evaluate the characteristics of the materials we supply that may be used for your proposed applications; however, Nexeo Plastics does not warrant the suitability or efficacy of the materials that we supply, and ultimately, you are responsible for and must make your own independent evaluation and judgment concerning the safety and efficacy of any materials supplied by Nexeo Plastics for use in your healthcare or other applications.

### TYPICAL HEALTHCARE REQUIREMENTS

#### Sterilization diversity

- Gamma, E-beam, autoclave and EtO

#### Biocompatibility\*

- ISO 10993 or USP Class VI or EP

#### Food contact compliance

- US FDA, European Food Safety Authority (EFSA), others

#### Chemical resistance

- Disinfectants, cleaners, lipids and IV solutions

#### Welding and bonding

- Ultrasonic, adhesive and solvent

### GENERAL MATERIAL CONSIDERATIONS

#### Optical clarity, colorability

- View fluids/contents, rapid identification and visual appeal

#### Impact resistance

- Ductility for practical use conditions
- Low-and high-temperature performance

#### Dimensional stability

- Tight tolerance/low creep

#### High flow and enhanced release

- Complex designs, low draft angles, thin wall and flow length capability

#### High-performance specialization

- Added strength, lubricity, shielding and anti-stat

#### Flame retardance

- UL 94-HB, V2, V1, V0, 5VB, 5VA
- RoHs flame retardant systems

#### Product stewardship

- REACH compliant products

## MATERIALS EXPERTISE FOR DIVERSE HEALTHCARE SEGMENTS

- Cardiovascular and blood care
- Drug delivery
- Fluid delivery
- Lab ware
- Nonwoven disposables
- Medical packaging
- Medical trays
- Monitoring and imaging
- Respiratory and medical tubes
- Orthopaedics
- Surgical instruments
- 3DP Technology in Healthcare

\* Biocompatibility: material evaluated based on ISO 10993 or USP Class VI protocol; supporting information available by Type I or Type II letter.



Cardiovascular and blood care

This segment encompasses handling and management of blood, such as during cardiovascular and orthopedic surgeries, blood donations and kidney dialysis treatments. Applications include devices to support extracorporeal systems, blood collection and separation, as well as equipment to move, filter and hold blood.



PERFORMANCE CONSIDERATIONS

- Biocompatible\* (devices)
- Chemical resistance
- Clarity (devices)
- EtO, gamma/E-beam and autoclave sterilization (devices)
- Good flow for processing (devices and membranes)

TYPICAL APPLICATIONS

- Blood collection and separation bowls
- Blood filter and membrane media
- Blood oxygenators and reservoirs
- Filters (leukocyte/arterial)
- Renal dialyzers

Drug delivery

Drugs come in diverse forms, requiring delivery devices that span a broad set of formats from injection to inhalation. Safety and patient compliance issues have led to increased use of needle-less techniques, focus on improved accuracy/efficiency in drug transfer, as well as aesthetic, miniaturized and ergonomic designs for drug-type identification and consumer appeal/use.



PERFORMANCE CONSIDERATIONS

- Biocompatible\*
- Clarity and colorability
- EtO, gamma and autoclave sterilization
- Formaldehyde-free valves
- Impact and wear resistance

TYPICAL APPLICATIONS

- Inhalers
- Insulin delivery devices
- Nebulizers
- Needle-less injection devices
- Syringes, bottles, tubes and vials

Fluid delivery

This segment includes handling and management of fluids for use in intravenous (IV) therapy and enteral (gastrointestinal) fluid delivery systems. These systems often include various pumps to facilitate fluid delivery to the patient and connection devices that integrate the fluid bag or bottle, pump and tubing into a single system.



PERFORMANCE CONSIDERATIONS

- Biocompatible\* (disposables)
- Chemical resistance (disposables and pumps)
- Clarity (disposables)
- EtO, gamma/E-beam sterilization (disposables)
- Impact resistance (pumps)

TYPICAL APPLICATIONS

- Fluid filters
- Infusion sets
- Stopcocks, luers, y-sites and check valves

Lab ware

The segment includes instruments and accessories for the analysis and diagnosis of patient samples, as well as for pharmaceutical and biopharmaceutical research. Applications range from disposable vials and containers for sample collection, to hand-held instruments, such as pipettors, for sample preparation, to clinical diagnostic equipment for rapid processing and evaluation of multiple samples.



PERFORMANCE CONSIDERATIONS

- Biocompatible\* (disposables)
- Clarity (disposables)
- Gamma and/or autoclave sterilization
- Impact and chemical resistance
- Light weight (equipment)

TYPICAL APPLICATIONS

- Cassettes, centrifuges and covers
- Diagnostic machines
- Diagnostic vial transport trays
- Pipettes, vials, tubes

\* Biocompatibility: material evaluated based on ISO 10993 or USP Class VI protocol; supporting information available by Type I or Type II letter.

Nonwoven disposables

Nonwoven disposables form an integral part of the healthcare market. Resistance, protection levels, disposability and the flexibility offered by materials that meet customer-specific needs are some of the major factors making nonwovens preferred over woven fabrics in hospitals and other contexts.



PERFORMANCE CONSIDERATIONS

- Colorability
- Sterility
- Strength and weight
- High filtration
- Resistance
- Breathability
- Sustainability/Recyclability

TYPICAL APPLICATIONS

- Medical gowns
- Disposable masks
- Plasters
- Swabs
- Baby nappies
- Incontinence products
- Surgical disposal
- Women's hygiene

Medical packaging

The industry has recognized the importance of good packaging design. Packaging has a significant role, from helping patients comply with medication requirements to helping companies meet regulatory requirements. We see continual innovation and improved material efficiency in this highly regulated industry.



PERFORMANCE CONSIDERATIONS

- Protects products from moisture, light, oxygen, and contaminants
- Solutions also include child-resistance, senior friendly packaging, and foil and non-foil barrier structures

TYPICAL APPLICATIONS

- Bottles
- Caps and closures
- Pouches
- Prefillable inhalers and syringes
- Blisters
- Vials and ampoules

Medical trays

Trays are used to transport instruments after surgery and to hold them during sterilization. In manufacturing, trays are used to transport vials and other items throughout the facility. Common to all types of trays is impact resistance to withstand unintended drops.



PERFORMANCE CONSIDERATIONS

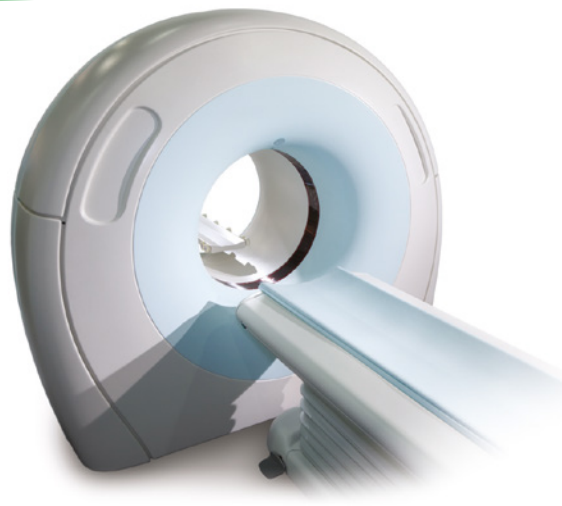
- Autoclave sterilization
- Biocompatible\*
- Chemical resistance
- Colorability
- Impact, crack, and craze resistance

TYPICAL APPLICATIONS

- Dental instrument trays
- Microsurgery and scope trays
- Surgical instrument trays
- Vial transport and storage trays

Monitoring and imaging

Monitoring and imaging devices are used in very diverse range of applications from hand-held and small devices, such as pulse oximeters, blood pressure and other patient monitors, to larger transportable devices, such as anesthesia delivery and ultrasound machines, to very large stationary equipment, such as x-ray, CT, MRI and PET imaging machines.



PERFORMANCE CONSIDERATIONS

- Chemical resistance to cleaners/disinfectants
- Colorability and indoor UV stability
- Durability, lightweight, and impact resistant
- Flame retardance and EMI/RFI shielding
- WEEE and RoHS complaint

TYPICAL APPLICATIONS

- Anesthesia delivery and monitoring
- OTC blood glucose meters
- Imaging equipment (e.g., MRI, CT, PET and x-ray)
- Patient monitors
- Portable monitoring devices

\* Biocompatibility: material evaluated based on ISO 10993 or USP Class VI protocol; supporting information available by Type I or Type II letter.



Respiratory and medical tubes

These devices and supporting equipment are used for treating respiratory-related illnesses in hospitals, clinics and at home. Respirators, ventilators, positive airway pressure devices and respiratory masks and connecting tubes assist a increasing number of patients who have ongoing therapy needs.



PERFORMANCE CONSIDERATIONS

- Biocompatible\* (airflow pathways)
- Clarity (masks)
- EtO and autoclave sterilization (masks and tanks)
- Flame retardance
- Impact and chemical resistance (masks and equipment)

TYPICAL APPLICATIONS

- Humidifier tanks
- Oxygen concentrators
- Positive Airway Pressure (PAP) devices
- Respirators and ventilators
- Respiratory masks and valves
- Respirator parts (filters, tubes, inhalers)

Orthopaedics

Orthopaedic devices support surgical and non-surgical techniques to preserve and/or restore the musculoskeletal system, limbs, etc. These devices use external fixators to immobilize the position of bones throughout the healing process.



PERFORMANCE CONSIDERATIONS

- Biocompatible\*
- Colorability
- Dimensional stability
- EtO, gamma and autoclave sterilization
- Impact and chemical resistance

TYPICAL APPLICATIONS

- Bone cement mixers
- External bone fixation devices
- Instrument handles
- Trays and cases

Surgical instruments

Due to the breadth of surgical techniques, a variety of tools have been developed to support specific procedures. These range from access devices to hand/mechanical and powered instruments for open and minimally invasive surgeries. As devices become smaller and more complex, the need for miniaturized components calls for specialized materials to achieve strength, durability and freedom of design.



PERFORMANCE CONSIDERATIONS

- Biocompatible\*
- Ductility and toughness
- EtO, gamma and autoclave sterilization
- Precision fit and high dimensional tolerance
- Smooth part interaction and low wear
- Strength and stiffness

TYPICAL APPLICATIONS

- Access devices
- Trocars, retractors and speculums
- Hand Instruments
- Staplers, forceps and clip appliers
- Powered Instruments
- Electrosurgical

3DP Technology in Healthcare

3D printing is becoming increasingly present in healthcare. Use of this technique is visible from conceptual modeling and prototyping of novel devices to training parts, advanced packaging and instruments. 3DP is also being incorporated in the production of end-use parts, facilitating a less expensive alternative to classical production, especially for small quantities and personalized patient-specific medical support.



PERFORMANCE CONSIDERATIONS

- Biocompatible\*
- EtO, Gamma and Steam (autoclave) sterilization
- Clarity or colorable
- Flame retardance
- Toughness and dimensional stability
- Traceability

TYPICAL APPLICATIONS

- Hearing aids
- Dental applications
- Models for virtual surgical planning and teaching
- PPEs
- Small production parts and replacements for medical devices
- Orthopaedics

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Dedicated Healthcare Grades

Supplier	Product Type	Grade	Medical Regulation <sup>(1)</sup>	Sterilisation Technique			MFR	Conversion Technique	Special Feature
				Steam	EtO	Gamma			
DSM	PBT	Arnite® Care T1U	USP, ISO 10993	Yes	Yes	Yes	24	IM	
DSM	PPA	ForTii® Care P1G6	USP, ISO 10993	Yes	Yes	Yes		IM	
DSM	TPC	Arnitel® Care L225E	USP, ISO 10993	Yes	Yes	Yes	48	IM	
DSM	TPC	Arnitel® Care L140E	USP, ISO 10993	Yes	Yes	Yes	33	IM	
DSM	TPC	Arnitel® Care L345A	USP, ISO 10993	Yes	Yes	Yes	10	EXT	
DSM	TPC	Arnitel® Care L155E	USP, ISO 10993	Yes	Yes	Yes	9	EXT	
Flint Hills Resources	PP-Homo	P4G3Z-039	DMF, USP	Yes	Yes	No	5	IM	
Flint Hills Resources	PP-Homo	P4G4A-053	DMF	Yes	Yes	No	12	IM	LTHA
Flint Hills Resources	PP-Homo	P4C5N-046	USP, DMF, ISO 10993	Yes	Yes	No	20	IM	NU
Flint Hills Resources	PP-Homo	P4C6B-134a	DMF	Yes	Yes	No	35	IM	AS, NU
Flint Hills Resources	PP-Ramdom	23R2A	USP, DMF, ISO 10993	Yes	Yes	Yes	2	EBM, IM	RAD
Flint Hills Resources	PP-Ramdom	23M2A	USP, DMF, ISO 10993	Yes	Yes	No	2	EBM, BFS, IM	
Flint Hills Resources	PP-Ramdom	P5M4K-046	USP, DMF	Yes	Yes	No	10	IM	AS
Flint Hills Resources	PP-Ramdom	13T25A	USP, DMF, ISO 10993	Yes	Yes	No	25	IM	
Flint Hills Resources	PP-Ramdom	P5M6K-080	USP, DMF, ISO 10993	Yes	Yes	Yes	27	IM	RAD
Flint Hills Resources	PP-Ramdom	P5M6K-048	USP, DMF	Yes	Yes	No	35	IM	
Lyondell Basell	PP-Homo	Pro-fax PF511	REACH, USP, DMF, EP	Yes	Yes	Yes	20	IM, EBM	Rad
Lyondell Basell	PP-Homo	Pro-fax PF531	REACH, USP, DMF, EP	Yes	Yes	Yes	27	IM, EBM	Rad
Lyondell Basell	PP-Homo	Pro-fax PD702	REACH, USP, DMF, EP	Yes	Yes	No	35	IM, EBM	
Mitsubishi	POM	lupital™ MAS20	USP, DMF, ISO 10993	No	Yes	No	9	IM	Standard
Mitsubishi	POM	lupital™ MAS30	USP, DMF, ISO 10993	No	Yes	No	27	IM	High Flow
Mitsubishi	POM	lupital™ MAH25	USP, DMF, ISO 10993	No	Yes	No	15	IM	High Rigidity
Mitsubishi	POM	lupital™ MAL20	USP, DMF, ISO 10993	No	Yes	No	8.6	IM	Low-Friction
Toray*	ABS	Toyolac™ 500-322M	ISO 10993	No	Yes	Yes	20	IM	High Rigidity
Toray*	MABS	Toyolac™ 950 ME1	USP, DMF, ISO 10993	No	Yes	Yes	18	IM	High Flow
Toray*	MABS	Toyolac™ 950 ME2	USP, DMF, ISO 10993	No	Yes	Yes	7	IM	High Chemical Resistance
SABIC 3DP Filament	PEI	ULTEM™ AMHU1010F	USP, ISO 10993	Yes	Yes	Yes		3DP	RAD
BASF 3DP Resin	Urethane photopolymer	Ultracur3D® RG35	ISO 10993	Yes	Yes	No		3DP	
BASF 3DP Resin	Urethane photopolymer	Ultracur3D® ST45	ISO 10993	Yes	Yes	No		3DP	
BASF 3DP Resin	Urethane photopolymer	Ultracur3D® ST80	ISO 10993	Yes	Yes	No		3DP	

(1)-Approval statement available on application via email: techrequest@nexeoplastics.com

\* Toray, available in France, Italy & United Kingdom only

USP = USA Pharmacopeia

EP = European Pharmacopia

DMF = Drug Master files

BFS = Blow-Fill-Seal

EBM = Extrusion Blow Moulding

IM = Injection Moulding

IBM = Injection Blow Moulding

ISBM = Injection Stretch Blow Moulding

Nu = Nucleation

Rad = Radiation

AB = Anti-block

AS = Anti-static

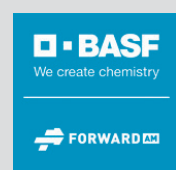
LTHA = Long-term heat acclimation

# Key Suppliers for other Applications and Markets

## Pan - European Suppliers



## 3DP Pan-European Suppliers



Nexo Plastics key suppliers are:  
Leaders in quality and reliability, focused on investing  
in their businesses, growth-oriented and connected globally.

## Local Suppliers \*



\* Not all the local suppliers are available in every country



## U.S. Food and Drug Administration (FDA) Drug Master File (DMF) and/or Device Master File (MAF)

Nexeo Plastics works with our suppliers to obtain U.S. FDA Drug Master Files and/or Device Master Files within the FDA's documentation centers for our healthcare products, where available. A Letter of Authorization (LoA) for the customer's reference of our Master Files and for the FDA's review of our Master Files may be provided upon request.

## U.S. FDA Food Contact Compliance

FDA grades comply with the requirements of the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations set forth by the FDA, covering substances used as basic components of food contact surfaces.

European Union (EU): EU food contact grades comply with the compositional requirements of Regulation (EU) No 10/2011 for plastics used in food contact applications.

## Implant policy

Nexeo Plastics does not support applications that involve implantation. Please refer to Nexeo Plastics' Healthcare Applications Policies for more details.

## Resin Biocompatibility

Typically, a set of tests are performed on a resin to determine if the resin or its extractables will cause potential harm to the human body.

Many of our suppliers' biocompatible grades have passed USP/USP Class VI biological tests or tests from the ISO 10993 "Biological Evaluation of Medical Devices."

Nexeo Plastics does not support the use of material grades not designated as "biocompatible supported" in healthcare applications requiring biocompatibility.

## Medical Devices Regulation (MDR) – EU Directive 2017/745/EU

The MDR, which aims to ensure a high level of quality and safety of medical devices, whilst supporting innovation, sets forth rules related to the market launch and commercialization of medical devices for human use and accessories for such devices and also applies to clinical investigations concerning such devices and accessories.

## In-vitro Diagnostics Regulation (IVDR) – EU Directive 2017/746/EU

The IVDR establishes a regulatory framework for in-vitro diagnostic devices, which aims to improve transparency and to maintain a high level of safety and quality for end users of these devices, while trying to balance the interests of the small and medium-sized enterprises that are active in this sector. The IVDR establishes general requirements of quality and safety for in vitro diagnostic medical devices in order to address common safety concerns in regard to such products.

## Restriction of Hazardous Substances (RoHS) – EU Directive 2011/65/EU

RoHS restricts the "use of certain hazardous substances in electrical and electronic equipment," including, but not limited to, lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs), unless specifically exempted. We offer materials that allow manufacturers to avoid the use of these hazardous substances in healthcare applications.

## UL 94, EN 60695-11-10/20, IEC 60695-11-10/20

One of the most widely accepted flammability performance standards for plastic materials are UL 94 ratings. These ratings are intended to identify a material's ability to extinguish a flame, once ignited. Several different ratings can be applied based on the rate of burning, time to extinguish, ability to resist dripping and whether or not drips are burning.

Each material tested may receive several ratings based on color and/or thickness. When specifying a material for an application, the UL rating should be applicable for the thinnest wall section in the plastic part, and the UL rating should always be reported with the thickness. EN 60695-11-10 is the European equivalent of UL 94; IEC 60695-11-10/20 is the international equivalent of UL 94.

## Waste Electrical and Electronic Equipment (WEEE) – EU directive 2012/19/EU

WEEE aims to promote sustainable production, efficient use of resources (including recycling), and reducing the environmental impact of WEEE. This Directive requires OEMs and component and sub-assembly producers providing electrical/electronics (E/E) products to the EU to collect, recover and treat these products at the end of life. Certain substances, mixtures, and components, including plastics using brominated flame retardants, must be removed from any collected WEEE and treated separately.

To help customers simplify recovery and recycling at end of life, we offer materials that are inherently flame-retardant or that do not contain brominated or chlorinated flame retardants.

## General Disclaimer

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# NEXEO PLASTICS

## EUROPE

Nexeo Plastics prides itself on providing its Customers with:

- Superior customer service (ISO certified)
- Broad product portfolio from world-class manufacturers
- Competitive pricing
- Geographic coverage
- Strong / long-term relationships
- Small / medium / large quantities
- Technical expertise in end applications
- Healthcare dedicated ADEs (Application Development Engineers)
- Flexibility to meet changing demand
- Efficient management & available inventory

- ◆ Warehouses
- Sales office



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