

Complete Compliance Pharmaceutical labelling solutions

Assured compliance and performance,
for any application



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Intelligent World.™

label.averydennison.eu/compliance

Meeting the regulations and guidelines of pharmaceutical packaging

All manufacturers of pharmaceutical packaging have to meet the challenges posed by new regulations and stronger packaging guidelines. There is growing pressure to understand rules in detail, and to make absolutely sure that every package is compliant.

Organisations that contribute to generating the regulations and guidelines for pharmaceutical packaging include the European Medicines Agency (EMA) and the International Organization for Standardization (ISO). These bodies oversee a wide range of regulatory mechanisms and standards, ensuring that products and services are safe, reliable and of good quality.

More regulations and more ISO norms mean that packaging manufacturers need to test different packaging material features, and provide complete documentation on the results.

What can we do for you?

- > Help you find the right labelling material for every application complying with necessary regulations
- > Provide customized test reports and documentation - and certifications where necessary

For example, any of the following may need to be taken into account when designing an application

- » Guidelines on plastic immediate packaging materials
- » Guidelines on medical devices, including toxicology and skin sensitization
- » Guidelines on blood bag labelling
- » Guidelines on functional packaging for hanging devices
- » Falsified Medicine Directive (FMD)

This all means rising demand from pharmaceutical companies for customised tests and certifications for individual packaging materials.

Avery Dennison's Pharma and Complete Compliance Expert Team gives converters and pharmaceutical companies detailed information, full transparency and technical support - essential resources when you are ensuring that your labelling applications are both successful and compliant.



Guidelines on plastic immediate packaging materials

Plastic-based containers are increasingly replacing glass containers and bottles for pharmaceutical packaging. They are more efficient, with fewer breakages and lower costs, and are especially convenient for small sizes or where squeezing is required.



However, migration is an issue for plastic containers. Components from inks, lacquer, top coats, adhesives, substrate (paper/film) or even the container itself may leach, and contaminate or react with the contents.

Regulatory authorities worldwide require studies, approvals and certifications. Since 2005, pharmaceutical companies have been invited to conduct tests based on the EMA 'Guideline on Plastic Immediate Packaging Materials', including extraction, interaction and migration studies for all new packaging materials.

Label and plastic packaging solutions should comply with:

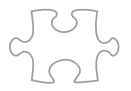
- > European food regulation **1935/2004/EC**, including **10/2011/EU** guidance on plastic materials and articles intended to come into contact with food
- > **ISO 3826** a norm that explains how to test plastics collapsible containers for human blood and blood components
- > **FDA 175.105** Food and Drug Administration (FDA) concerning indirect food additives, adhesives and components of coatings

Avery Dennison has developed several pharmaceutical labelling adhesives that follow the guidelines on plastic immediate packaging materials:

	Adhesives		
	S2000NP	S692NP	S717P
Regulation 1935/2004/EC	✓	✓	✓
ISO 3826	✓	✓	✓
FDA 175.105	✓	✓	✓
Drug Master File (DMF)	-	✓	✓

In addition, Avery Dennison has responded to growing requests for extraction testing of adhesives, and can provide adhesive analysis reports meeting the European norm standards EN 1186, EN 13130 and CEN/TS 14234, 14235. Customised tests for individual packaging materials are conducted, and we offer close support for companies who need to evaluate any label construction for a particular application. Assistance can be provided rapidly.

* Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes or articles used in manufacturing, processing and storing of human drugs.



Guidelines on medical devices including toxicology and skin sensitization

For any medical devices such as auto injectors, or for any materials in contact with a patient, biological evaluation and biocompatibility testing are needed. This testing assesses interactions with a patient's tissues, cells or body fluids - and helps to prevent potential biological risks.



The relevant testing standard is ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process'. The exact test deployed depends on the type of device and application, including how long the device will remain in contact with the patient. Factors considered include irritation, cytotoxicity and sensitization.

Two tests we consider to be most relevant for labelling materials to meet this Evaluation and Testing within a Risk Management Process (ISO 10993-1) are:

- > **ISO 10993-5** dedicated test for vitro cytotoxicity
- > **ISO 10993-10** test for irritation and skin sensitization

Avery Dennison has developed several pharmaceutical labelling adhesives that comply with ISO 10993, 'Biological Evaluation of Medical Devices' :

	Adhesives	
	S692NP	S717P
ISO 10993 - Part 5	✓	✓
ISO 10993 - Part 10	-	✓

Some countries also require statements of 'Latex-free' and 'BPA-free'.



General information on issues affecting compliance in the labelling industry is available at label.averydennison.eu/compliance

Please contact your sales representative if you have any questions.



Guidelines on blood bag labelling

Blood processing and transportation require specialised label materials that can not only withstand the rigorous lifecycles of blood and plasma bags, but also communicate critical information about origins and content.



The global ISBT 128 standard applies, designed to ensure the highest levels of accuracy, safety, and efficiency for donors and patients worldwide. Labels must also comply with food regulations, and the requirements of ISO 3826: 'Plastics collapsible containers for human blood and blood components'.

Legislation that label and packaging solutions should comply with includes:

- > **ISO 3826** certification on migration behaviour for blood bags
- > **FDA 175.105** indirect additives, adhesives and components of coatings

Avery Dennison has developed several pharmaceutical labelling adhesives that follow guidelines on blood bag labelling, and which may be suitable for individual blood bag applications:

	Adhesives		
	AL171	C2020P	S2060NP
ISO 3826	✓	✓	✓
FDA 175.105	✓	✓	✓



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Guidelines on functional packaging for hanging devices

Several ISO norms have been set to ensure that transfusion and infusion bottles stay firmly in place during the administration of liquid pharmaceutical products.

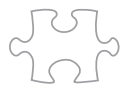
In particular for hanging devices, international standards ISO 15137, ISO 15010 and DIN 58369 describe requirements and test methods for self-adhesive hanging devices (SAHDs). Finished labels need to comply with several requirements such as label attachment, load and water resistance.

In this case, there is no legislation and there are no standard certifications available, but each labelling solutions requires its own customised testing. Avery Dennison supports the development process closely, helping converters to evaluate finished labels. We conduct individual assessments following test standard protocols for self-adhesive hanging devices (SAHD) based on ISO and DIN conditions.



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Guidelines on Falsified Medicine Directive (FMD)

Drug counterfeiting is a growing problem for both pharmaceutical manufacturers and the patients they serve. Manufacturers of these drugs experience damage to their brand image, sales and revenue.



The European Union has set guidelines for “Falsified Medicines”, amending Directive [2011/62/EU](#), in order to prevent falsified medicines entering the legal supply chain and reaching patients. Directive 2011/62/EU in article 54(o), which will come into force on Feb 19th 2019, requires that for medicinal products other than radiopharmaceuticals it should be possible to verify whether or not the outer packaging has been tampered with. This applies to all prescription and some over the counter products.

In this case, there are no standard certifications available, but labelling solutions require their own customised testing. Avery Dennison supports the development process closely, helping converters to evaluate finished labels. We conduct individual assessments following our own test protocols to meet the conditions described in EN 16679.

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Your puzzle solved

With Avery Dennison® Complete Compliance

For detailed information including certification and more on food approval see:

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2017-05_15152EN



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