Green Mark	**Plastic Intravenous Fluid Containers**	No. 96 Category No. E-02

1. Scope

This standard is applicable to plastic intravenous fluid containers ("products"), including associated parts and components, such as stoppers, caps, and connectors.

2. Terms and definitions

For the purpose of this standard, the following terms and definitions shall apply.

Phthalate esters (PAEs): Include di(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DNOP), dimethyl phthalate (DMP), dibutyl phthalate (DBP), denzyl butyl phthalate (BBP), di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP) and diethyl phthalate (DEP).

3. Product characteristics

3.1 The product materials shall not contain chlorinated plastics, and the product's content of chlorine shall be below the regulatory limit.

3.2 The product materials' content of tin, lead, and cadmium shall be below the regulatory limits.

3.3 The product materials' content of phthalate esters shall be below the regulatory limit.

3.4 The adhesive used in products with multilayer membranes shall not contain hazardous substances assigned the following hazard classifications by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS): H300, H301, H310, H311, H330, H331, H334, H340, H341, H350, H351, H360, H361, H370, H372, H373, H400, H410, H411, and H412. The applicant shall provide the adhesive's material safety data sheet (MSDS) for review. The MSDS shall contain the ingredients' names, CAS Nos. and applicable GHS hazard classifications, as well as relevant hazards and precautionary information.

3.5 The product and its manufacturing processes shall not use substances stipulated by the Taiwan EPA as toxic substances, and substances controlled by the Montreal Protocol.

Date of Promulgation: December 15, 2006	Environmental Protection Administration, Executive Yuan, R.O.C. (Taiwan)	Date of Latest Revision: November 1, 2018

4. Test methods and regulatory limits

The regulated substances and regulatory limits for this standard are listed below. The applicable test methods shall be the national, international or specific industry standard methods, and the test reports shall be issued by accredited professional testing organizations.

Applicable Content	Regulated Substance	Regulatory Limit	Referenced Test Method
Plastic	chlorine	＜260 mg/kg	NIEA M402 EN 14582
Plastic	tin	＜2 mg/kg	NIEA M104 NIEA M105 NIEA M353 US EPA 3050 US EPA 3051
Plastic	lead	＜2 mg/kg*	NIEA M353 NIEA M301 CNS 15050 US EPA 3050 US EPA 3051 US EPA 3052
Plastic	cadmium	＜2 mg/kg*	NIEA M353 NIEA M301 CNS 15050 US EPA 3050 US EPA 3051 US EPA 3052
Plastic	phthalate esters	＜10 mg/kg*	NIEA M731 CNS 15138-1 Test method for food containers and packaging, promulgated by Ministry of Health and Welfare

*: The test report shall provide evidence that the employed test methods have detection limits of less than 1/3 of the regulatory limits.

5. Packaging

The materials of the product packaging shall meet the requirements of the *Guidelines on Review of Applications for Qualified Environmental Protection Products*.

6. Labeling

6.1 The name, address and consumer hotline of the Green Mark user shall be clearly printed on the product or product packaging.

6.2 The product or product packaging shall bear a label reading "Low Pollution".

7. Other requirements

For products with the same drug permit, they are considered the same if they use the same kinds of materials but differ only in the container size.

Revision History:

First revision: February 13, 2014

Second revision: November 1, 2018