Hospira, Inc.
Technical Operations

EMEA TECHNICAL DATA SHEET

TITLE	TECHNICAL DATA SHEET: 0G713, 0G714, 0G715, 0G716, 0G717, 0G718, 0G719, 0G720, 0G944		
LIST NUMBER	0G713	**EFFECTIVE DATE**	03-18-09
LEGAL MANUFACTURER	**Hospira, Inc., Lake Forest, IL USA**		

DESCRIPTION	Abbocath-T is a sterilized intravenous catheterization device consisting of a catheter fitted over a needle with a transparent luer connection and air filter. The catheter and needle are protected by a plastic sheath
USE/INDICATION	These devices are intended to be used for the intravascular administration of medicinal and I.V. solutions and for the administration or extraction of blood and body fluids.
DRAWING	IC116410
	
MATERIALS OF CONSTRUCTION	This product contains no natural rubber and is LATEX FREE. This product does not contain DEHP. High molecular weight polymers are used in the manufacture of these products. The materials of construction are not chemically active under recommended conditions of use. Typical materials of construction: Acrylonitrile Butadiene Styrene, Polyethylene, Acrylic Multipolymer, Polypropylene, Co-polyester, Polytetrafluoroethylene, Polycarbonate, Stainless Steel, and fluorinated ethylene propylene
PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging is according to BS EN ISO 11607. The packaging for this product is Latex Free.
STERILIZATION METHOD	EO, according to ISO 11135.
SHELF LIFE	60 Months

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BIOCOMPATIBILITY	Product has been approved for use as an I.V. infusion medical device and has passed biocompatibility testing with no toxic reactions recorded.
LABELING	Labeling is developed in accordance with BS EN 980:2003, BS EN 1041:1998. International Labeling and Specification Development SOP 39B-0084; is maintained following Approval Requirements for Change Requests Procedure QCD.04.002. The Risk Management Report is reviewed for potential hazards/harm that need label mitigation.
INSTRUCTIONS FOR USE	Label contains information for proper use including any warnings or contraindications .
MANUFACTURING ENVIRONMENT	Product is manufactured in a clean room that complies with Chinese GMP (1998), appendix 1.
TRACKING	Each single product is identified by a unique list number assigned to a unique finished product batch record number, and tracked through all the stages of the production process including release to market.
STORAGE CONDITION	Store in a dry, ambient temperature and humidity conditions. No unusual handling instructions apply. Product should be retained in its provided packaging until ready for use.
QUALITY TESTS	Final product is tested per Hospira specifications at the manufacturing plant and maintained for six years.
QUALITY SYSTEM AND PRODUCT CERTIFICATION **(Check for current validity)**	**Quality System is in compliance to:** ISO 13485:2003 **Quality System Certificate Number:** CM19.3788 **Certify Body: NSAI National Standards Authority of Ireland** **FDA Approved: 510 (K):** n/a International set only **Product Certification: *:*** It is manufactured in compliance to Council Directive MDD/93/42EEC **CE Certificate Number:** 252.113 CE 0050 **Certify Body: NSAI National Standards Authority of Ireland** **Device Classification:** Class IIa (according to Annex IX Rule 7 per MDD/93/42/EEC)
DESCRIPTION OF CHANGE **CR 09-79** **(D. Threats)** **PLT # 0439RD08**	New Document.

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