PRODUCT TECHNICAL DATASHEET

ITEM REF:	21-6120-24	REVISION	118

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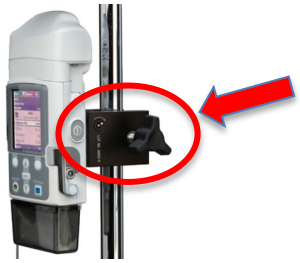
LEGAL MANUFACTURER	**Smiths Medical ASD Inc.** 6000 Nathan Lane North Minneapolis, Minnesota 55442 USA
IMPORTER	**Smiths Medical Nederland** B.V. Hofspoor 3, 3994 VZ Houten, The Netherlands
EU AUTHORIZED REPRESENTATIVE (EUAR)	**Smiths Medical Czech Republic a. s., Olomoucka** 306, Hranice 1 - Mesto, 753 01 Hranice, Czech Republic
ASSEMBLY SITE	**Chandler Industries – Blaine Division** 8650 West 35W Service Drive Blaine, MN 55449
CLASSIFICATION CODE	N/A
INTENDED USE	Lockable rod pump clamp allows you to mount a CADD® pump, a "Lockbox" container or a pump safety container on an IV pole. It is designed to be attached directly to the back of a pump or pump safety container, or a "Lockbox" container. To attach the CADD-Legacy® and CADD-Solis® pumps to an IV pole, the appropriate adapter is required.
ITEM DESCRIPTION	POLEMOUNT BRACKET, LOCKABLE, CADD 1/EA
QUANTITY PER PACK	1
	
PRODUCT-SPECIFIC DATA	Contains metal components
CONFORMITY OF THE MATERIAL AND BIOCOMPATIBILITY	The product meets the biocompatibility requirements of ISO 10993-1 and related standards.
PRECAUTIONS	For a complete list of applicable warnings and precautions, see the instructions for use.
LABELS/INSTRUCTIONS FOR USE	The label and/or instructions for use contain the information necessary for the correct use of the product, including any warnings and contraindications. Labels are applied to the individual bags and to the outer side of the cardboard box. Each package for sale contains a copy of the instructions for use.
PACKAGING AND PACKAGING	The packaging complies with the requirements of BS EN ISO 11607. The packaging of this product is latex-free. This item is individually packaged in blister packs or pouches with medical grade materials.

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TRACEABILITY	All operations are equipped with procedures for the traceability of products and goods. These procedures contain provisions for quality control and proper segregation of components/products, to avoid mixing of products or components. Procedures for checking components and product identification and batch numbering have been established as part of the control and traceability process.	
DISPOSAL	Dispose of the device in accordance with hospital disposal policies.	
PRESERVATION	Store in a dry and clean place. The product should be stored in the packaging until ready to use.	
PRODUCTION CONTROLS	Products are manufactured under controlled conditions, described in written policies and procedures that provide a comprehensive Quality Management System (QMS), within the scope of Quality Systems Regulation (QSR).	
QUALITY SYSTEM AND PRODUCT CERTIFICATION	**The quality system complies with:**	ISO 13485:2016
	Product Certification:	The product is manufactured in accordance with the Council MDD Directive 93/42/EEC and subsequent amendments.
	CE Certificate Number :	N/A
	Notified body:	N/A
	MDD classification of the medical device:	N/A