

Product data sheet

CADD Extension Set

1. Company data

1.1. Manufacturer:

Name Smiths Medical MD, Inc
Address 1265 Grey Fox Road, St Paul, MN 55112
Country USA
Website www.smiths-medical.com

1.2. Distributor:

Name Astra Tech A/S
Address Husby Allé 19, 2630 Taastrup
Phone no. +45 4371 3377
Fax no. +45 4371 7865
E-mail info.dk@astratech.com
Website www.astratech.dk

Quality management systems:

Manufacturer: ISO 13485, ISO 9001:2000

Distributor: _____

2. Product

2.1 Trade name CADD Extension Set

2.2. List of product range:

[See "Product range" \(if Excel file\)](#)

["Click here" \(if web based\)](#)

2.3. More information about the product

[See "More information" \(if Excel file\)](#)

["Click here" \(if web based\)](#)

3. Product components

(For sterile products **including** the item package/sterile barrier)

Cardboard: ☐	Paper: ☒	Glass: ☐
Metal: ☐	Latex: ☐	Cotton: ☐
Other: _____		Organic: ☐

3.2. Plastics:

Types of plastic: Refer to Instructions for Use PVC: ☒

If PVC, state plasticiser: TOTM % of PVC: ~30%

3.3. Heavy metals, chlorine, etc.:

Heavy metals: ☐ Types: _____

Chlorine bleached material: ☐ Recycled materials: ☐

Are substances from the Environmental Agency's list of undesirable substances included? : ☐

State substances: Note: By agreement with Sinerfa, this point takes effect only from 1 June 2003!!

4. Packaging components

(For sterile products **excluding** the item package/sterile barrier)

Cardboard: ☐ X

Paper: ☐

Glass: ☐

Metal: ☐

Latex: ☐

Cotton: ☐

Organic: ☐

Other: Tyvex

4.2. Plastics:

Types of plastic: _____

PVC: ☐

If PVC, state plasticiser: _____

% of PVC: _____

4.3. Heavy metals, chlorine, etc.:

Heavy metals: ☐

Types: _____

Chlorine bleached material: ☐

Recycled materials: ☐

State any substances from the Environmental Agency's list of undesirable substances: _____

Note: By agreement with Sinerfa this point takes effect only from 1 June 2003!!

5. CE marking

5.1. CE mark: No: ☐ Yes: ☒ Class: Ila

6. Environmental information

6.1. Does a recognised env. label exist for the product area? Yes: ☐ No: ☒

6.2. Does the product carry an environmental label? No: ☒ Yes: ☐ Label: _____

6.3. Environmental management systems: (State recognised environmental management systems, if any)

Manufacturer: _____ Distributor: _____

7. Shelf life

Shelf life after date of manufacture / date of sterilisation:

8. Recommended storage and handling

State recommendations _____

9. Recommendations for waste handling

Recommendation = X	Incineration	Landfill	Recycling	Recycling label
Product	X			
Item package		X		
Inner package		X		
Transport packaging			X	

Name of product /product category

CADD Extension Set

Manufacturer product no.	Distributor product no.	EAN no. sales unit	Description	Size	Packaging unit	No. of packs per trsp carton	No. of cartons per pallet	Ste- rile
21-7040-24	DK21704024		CADD Extension set 55" TOTM-plasticized Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve, and Clamp	55"	Tyvek Pouch, Corrugated Box	25		*
21-7045-24	DK21704524		CADD Extension set 30" with Male/Male Luers, Integral Anti-siphon Valve, and Clamp	30"	Tyvek Pouch, Corrugated Box	50		*
21-7046-24	DK21704624		CADD Extension set 45" with Male/Male Luers, Integral Anti-siphon Valve, and Clamp	45"	Tyvek Pouch, Corrugated Box	50		*
21-7047-24	DK21704724		CADD Extension set 60" with Male/Male Luers, Integral Anti-siphon Valve, and Clamp	60"	Tyvek Pouch, Corrugated Box	50		*
21-7106-24	DK21710624		CADD Extension set 60" TOTM-plasticized Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve, and Clamp	60"	Tyvek Pouch, Corrugated Box	50		*

Instructions:

There must be an EAN no. for each possible sales unit

The description may be the text of the distributor's invoice / delivery note

The size concept varies for different product areas, for instance S-M-L for absorbent pads, measurements, weight and ch for catheters, etc.

A packaging unit is for instance the number of items, rolls, cans, ml or similar.

Indicate sterile products by means of an *