

Enteral Data Sheet

Revision 3.1

Ref Doc: PSD0016		No.: ELDISO-XH2 & EISO-XXH2		Rev. 4
Product:	ISOSAF Home 2 Syringes		Application:	Enteral
Technical Qualification				
Raw Materials:	Barrel - Polypropylene		Plunger (2.5ml-100ml) - Polypropylene	
	Plunger (1ml) - HDPE		Lubricant- Silicone Oil	
	Gasket- Polyisoprene Rubber		Printing Ink – PPE/ PPO Ink Series	
Packing:	Primary - Medical Dialysis Paper, PP/PE Medical composite packaging film			
	Secondary - Hard Corrugated Paper			
	Tertiary - Double Corrugated Paper			
Regulatory:	Class I S&M – 1ml, 2.5ml & 100ml Class IIa – 5ml - 60ml			
Others:	Shelf Life – 5 years EO Sterilisation Latex free			
Products:				
Code:	Description:			
ELDISO-1H2	ISOSAF 1ml Low Dose Home 2 ENFit Syringe			
ELDISO-2.5H2	ISOSAF 2.5ml Low Dose Home 2 ENFit Syringe			
ELDISO-5H2	ISOSAF 5ml Low Dose Home 2 ENFit Syringe			
EISO-10H2	ISOSAF 10ml Home 2 ENFit Syringe			
EISO-20H2	ISOSAF 20ml Home 2 ENFit Syringe			
EISO-60H2	ISOSAF 60ml Home 2 ENFit Syringe			
EISO-100H2	ISOSAF 100ml Home 2 ENFit Syringe			
Intended Use:				
These medical devices are intended for use in combination with other devices that employ the ISO 80369-3 International Standard design for Small Bore Connectors. These devices are used as enteral syringes for medical use. This product is single patient use.				
Pictures:				
<i>Examples:</i>				
				

Packaging:		
Code:	Packing:	Units:
ELDISO-1H2	Primary – Blister 33mm (H) x 11.8mm (W) x 134mm (D)	1
	Secondary – Shelf Box 95mm (H) x 130mm (W) x 220mm (D)	100
	Tertiary – Shipper Carton 465mm (H) x 410mm (W) x 600mm (D)	3600
ELDISO-2.5H2	Primary – Blister 36mm (H) x 13.35mm (W) x 122mm (D)	1
	Secondary – Shelf Box 125mm (H) x 135mm (W) x 215mm (D)	100
	Tertiary – Shipper Carton 530mm (H) x 450mm (W) x 565mm (D)	3200
ELDISO-5H2	Primary – Blister 39.6mm (H) x 17.6mm (W) x 125mm (D)	1
	Secondary – Shelf Box 175mm (H) x 140mm (W) x 225mm (D)	100
	Tertiary – Shipper Carton 550mm (H) x 470mm (W) x 580mm (D)	2400
EISO-10H2	Primary – Blister 44mm (H) x 20.8mm (W) x 147mm (D)	1
	Secondary – Shelf Box 115mm (H) x 170mm (W) x 390mm (D)	100
	Tertiary – Shipper Carton 535mm (H) x 410mm (W) x 600mm (D)	1500
EISO-20H2	Primary – Blister 57mm (H) x 23.5mm (W) x 165mm (D)	1
	Secondary – Shelf Box 170mm (H) x 180mm (W) x 420mm (D)	100
	Tertiary – Shipper Carton 535mm (H) x 435mm (W) x 560mm (D)	900
EISO-60H2	Primary – Blister 67.5mm (H) x 36.5mm (W) x 205mm (D)	1
	Secondary – Shelf Box 175mm (H) x 225mm (W) x 370mm (D)	50
	Tertiary – Shipper Carton 378mm (H) x 385mm (W) x 470mm (D)	200
EISO-100H2	Primary – Blister 80mm (H) x 39.4mm (W) x 252mm (D)	1
	Secondary – Shelf Box 125mm (H) x 275mm (W) x 435mm (D)	30
	Tertiary – Shipper Carton 275mm (H) x 290mm (W) x 450mm (D)	60

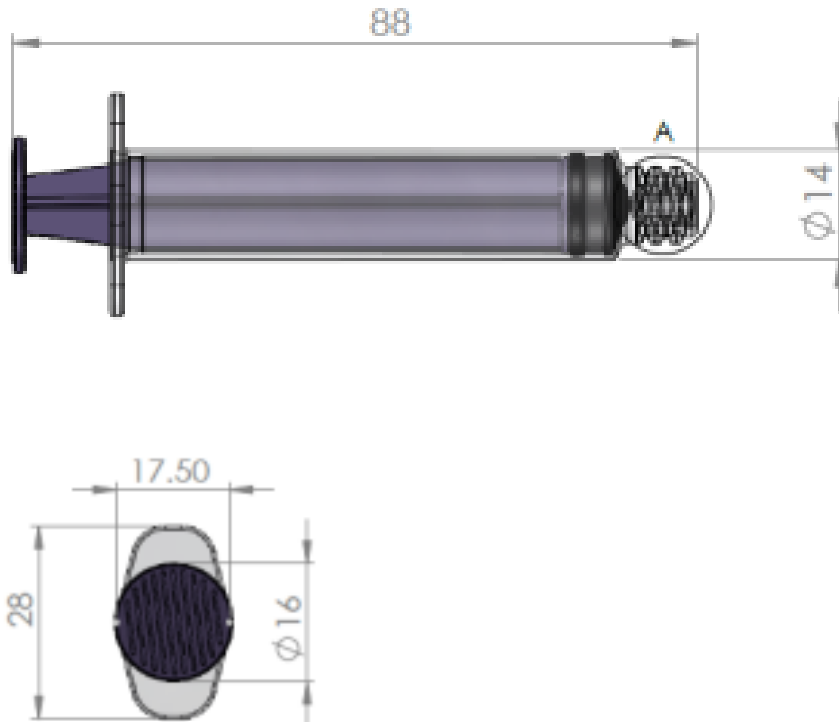
Code:	GTIN Primary:	GTIN Secondary:	GTIN Tertiary:
ELDISO-1H2	05060590881590	05060590881606	05060590881613
ELDISO-2.5H2	05060590881620	05060590881637	05060590881644
ELDISO-5H2	05060590881651	05060590881668	05060590881675
EISO-10H2	05060590881682	05060590881699	05060590881705
EISO-20H2	05060590881712	05060590881729	05060590881736
EISO-60H2	05060590881743	05060590881750	05060590881767
EISO-100H2	05060590881774	05060590881781	05060590881798

Code:	Quantity per Pallet:	Pallet Dimensions:
ELDISO-1H2	28800	1200mm x 1000mm
ELDISO-2.5H2	25600	1200mm x 1000mm
ELDISO-5H2	19200	1200mm x 1000mm
EISO-10H2	12000	1200mm x 1000mm
EISO-20H2	7200	1200mm x 1000mm
EISO-60H2	3600	1200mm x 1000mm
EISO-100H2	1920	1200mm x 1000mm

Drawings:

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Description: Primary Artwork

Figure 1: ELDISO-1H2

*** Variations: ELDISO-2.5H2, ELDISO-5H2 ***

Figure 2: EISO-10H2

*** EISO-20H2, EISO-60H2, EISO-100H2 ***

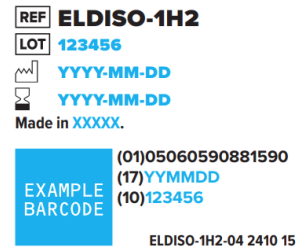


Figure 1

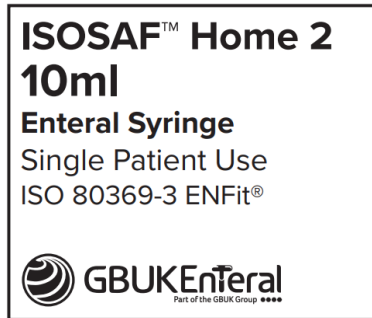


Figure 2

Description: Secondary Artwork

Figure 3: ELDISO-1H2

*** Variations: ELDISO-2.5H2, ELDISO-5H2 ***

Figure 4: EISO-10H2

*** EISO-20H2, EISO-60H2, EISO-100H2 ***



Figure 3



Figure 4

Description: Tertiary Artwork

Figure 5: ELDISO-1H2

*** Variations: ELDISO-2.5H2, ELDISO-5H2 ***

Figure 6: EISO-10H2

*** EISO-20H2, EISO-60H2, EISO-100H2 ***

Figure 5



Figure 6

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