InfusoSafe™ Set P Dedicated Administration Sets Technical Datasheet

For nVP and eVP PVC dedicated infusion pump





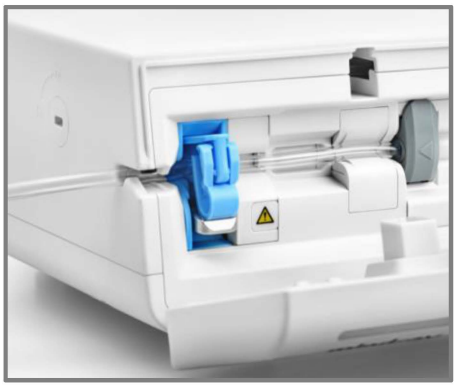
Designed with safety in mind

The InfusoSafe™ Set P dedicated administration sets portfolio has configurations to suit the majority of IV infusion needs. Options include standard PVC sets, light protected sets for light sensitive medication, and sets with in-line air eliminating fine filters. All sets are non-pyrogenic, DEHP-free, Latex-free, and supplied with protective end caps.



InfusoSafe™ Clamp

Provides pump-activated free flow protection, and the colour coding on the pump clamp slot makes set loading more intuitive.



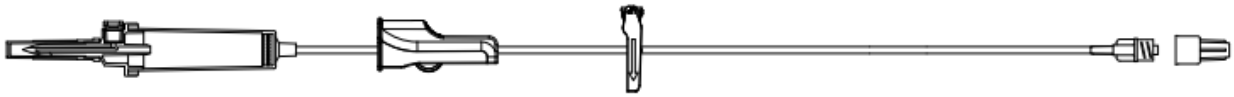
Needle free port

A flat top surface for efficient disinfection. The clear housing enables visualisation of the fluid pathway.





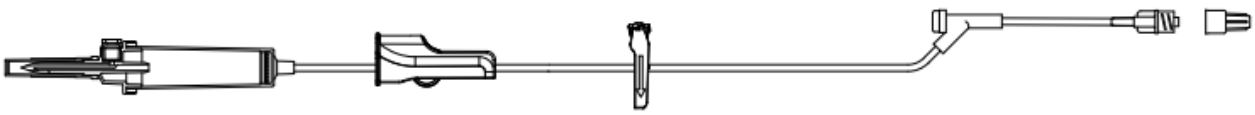
InfusoSafe™ Set P Technical Datasheet – X-IS-000D

Set description on label	Infusion Set, 15µm
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller Clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	235 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total priming volume: 22mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
Country of manufacture/origin	China
CE and Authorized Representative	MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany CE 0123
Quality system	ISO13485 TÜV SÜD Product Service GmbH

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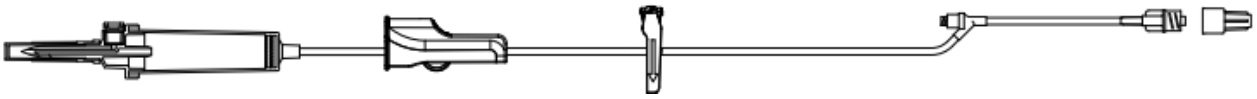


InfusoSafe™ Set P Technical Datasheet – X-IS-001D

Set description on label	Infusion Set, 15µm, injection site (latex-free)
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Injection Y Port (latex-free), Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
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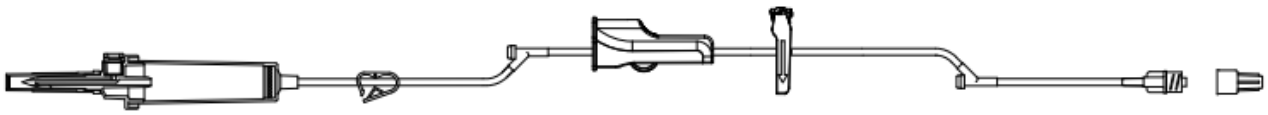
InfusoSafe™ Set P Technical Datasheet – X-IS-002D

Set description on label	Infusion Set, 15µm, needle free port
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Needle free port, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
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InfusoSafe™ Set P Technical Datasheet – X-IS-003D

Set description on label	Infusion Set, 15μm, 2 injection sites (latex-free)
Detailed description	Vented-Spike (5μm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15μm filter, Pinch Clamp, Upstream Injection Y Port (latex-free), Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Downstream Injection Y Port (latex-free), Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 24mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
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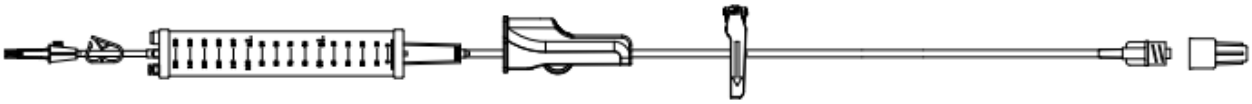


InfusoSafe™ Set P Technical Datasheet – X-IS-004D

Set description on label	Infusion Set, 15µm, 4 needle free ports
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Pinch Clamp, 4*Needle free ports, Drip chamber-20 drops/mL, 15µm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	240 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 22mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
Country of manufacture/origin	China
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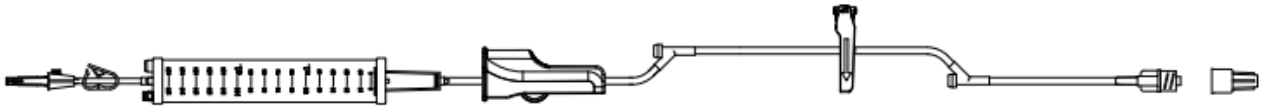
InfusoSafe™ Set P Technical Datasheet – X-BS-005D

Set description on label	Infusion Set, burette, 15μm
Detailed description	Vented-Spike (5μm hydrophobic air inlet filter), Pinch Clamp, 150mL burette with float valve, Drip chamber-20 drops/mL, 15μm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 90 ea/box (6 inner cases of 15 ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
Country of manufacture/origin	China
CE and Authorized Representative	MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany CE 0123
Quality system	ISO13485 TÜV SÜD Product Service GmbH

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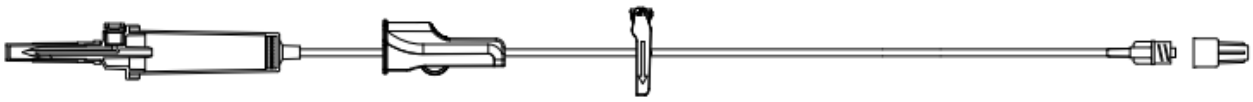


InfusoSafe™ Set P Technical Datasheet – X-BS-003D

Set description on label	Infusion Set, burette, 15μm, 2 injection sites (latex-free)
Detailed description	Vented-Spike (5μm hydrophobic air inlet filter), Pinch Clamp, 150mL burette with float valve, Drip chamber-20 drops/mL, 15μm filter, Roller clamp, Upstream Injection Y Port (latex-free), InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Downstream Injection Y Port (latex-free), Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 90 ea/box (6 inner cases of 15 ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
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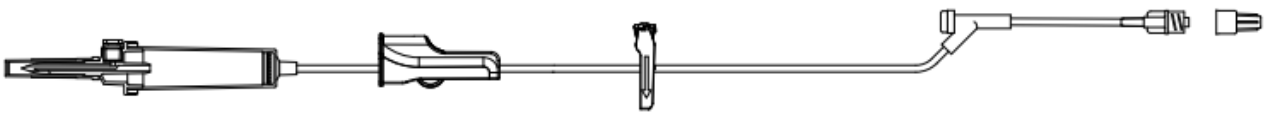
InfusoSafe™ Set P Technical Datasheet – X-LS-000D

Set description on label	Infusion Set, light protected, 15µm
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller Clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm light protecting PVC tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	235 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 22ml
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
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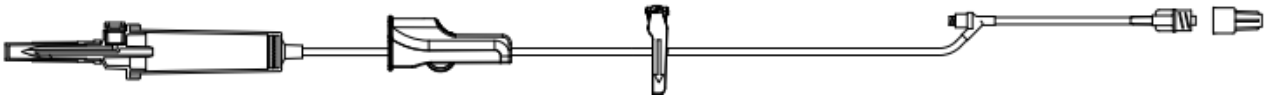


InfusoSafe™ Set P Technical Datasheet – X-LS-001D

Set description on label	Infusion Set, light protected, 15µm, injection sites (latex-free)
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC light protecting tubing, Injection Y Port (latex-free), Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
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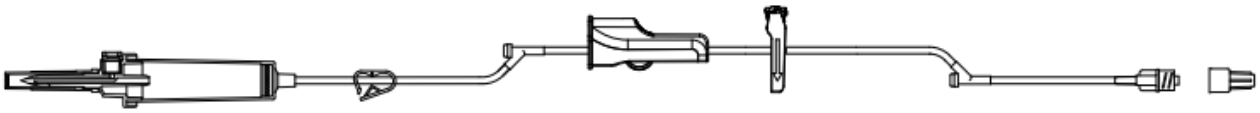


InfusoSafe™ Set P Technical Datasheet – X-LS-002D

Set description on label	Infusion Set, light protected, 15µm, needle free port
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC light protecting tubing, Needle free port, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
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Quality system	ISO13485 TÜV SÜD Product Service GmbH



InfusoSafe™ Set P Technical Datasheet – X-LS-003D

Set description on label	Infusion Set, light protected, 15µm, 2 injection sites (latex-free)
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Pinch Clamp, Upstream Injection Y Port (latex-free), Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm light protecting PVC tubing, Downstream Injection Y Port (latex-free), Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 24mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
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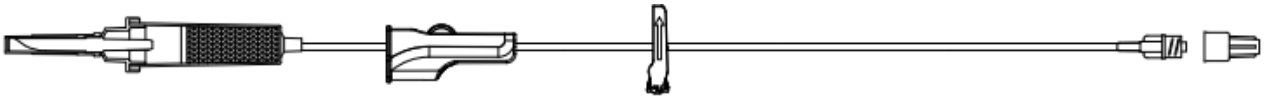


InfusoSafe™ Set P Technical Datasheet – X-LS-004D

Set description on label	Infusion Set, light protected, 15µm, 4 needle free ports
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Pinch Clamp, 4*Needle free ports, Drip chamber-20 drops/mL, 15µm filter, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC light protecting tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	240 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 22mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
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Quality system	ISO13485 TÜV SÜD Product Service GmbH



InfusoSafe™ Set P Technical Datasheet – X-TS-000D

Set description on label	Blood transfusion set, 200μm
Detailed description	Non-vented spike, 200μm fluid filter, Drip chamber-20 drops/mL, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For blood transfusion
Set length cms	235 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 25mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
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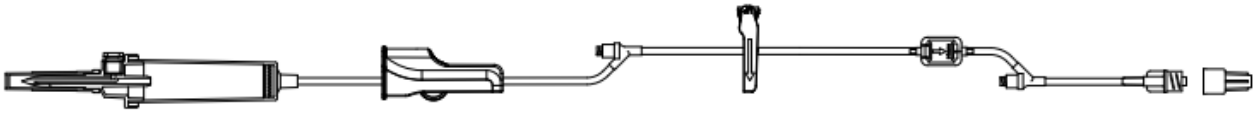


InfusoSafe™ Set P Technical Datasheet – X-ES-000

Set description on label	Secondary infusion set, 15µm
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), 15µm filter, Drip chamber-20 drops/mL, Roller clamp, 3*4mm PVC tubing, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	95 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 12mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
Country of manufacture/origin	China
CE and Authorized Representative	MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany CE 0123
Quality system	ISO13485 TÜV SÜD Product Service GmbH

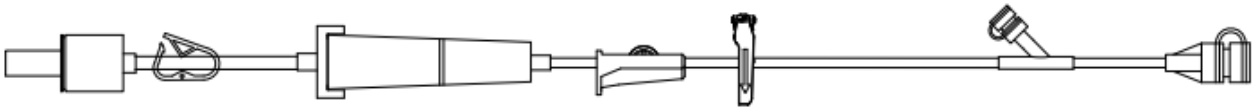


InfusoSafe™ Set P Technical Datasheet – X-IS-103D

Set description on label	Infusion set, 1.2µm filter, 2 needle free ports
Detailed description	Vented-Spike (5µm hydrophobic air inlet filter), Drip chamber-20 drops/mL, 15µm filter, Roller clamp, Upstream needle free port, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, 1.2µm anti-bacterial and air eliminating filter, Downstream needle free port, Rotating male Luer Lock, Protection cap
	
Intended use	For intravenous infusions
Set length cms	250 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40°C), 8ml (40°C/2bar) Total Priming Volume: 26mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
Country of manufacture/origin	China
CE and Authorized Representative	MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany CE 0123
Quality system	ISO13485 TÜV SÜD Product Service GmbH



InfusoSafe™ Set P Technical Datasheet – X-EN-002D

Set description on label	Enteral nutrition set, Y-port
Detailed description	Non-vented Enteral Cross Connector, Pinch Clamp, Drip chamber-20 drops/mL, Roller clamp, InfusoSafe™ Clamp free flow protection clamp, 3*4mm PVC tubing, Enteral Y-connector with cap, Enteral patient connector, Protection cap
	
Intended use	For enteral feeding
Set length cms	235 cm
Priming volume mLs 40C/40C and 2 Bar pressure Total Priming Volume	7ml (40℃), 8ml (40℃/2bar) Total Priming Volume: 23mL
Is the product DEHP free and latex free?	Yes
Lipid/alcohol resistant?	Yes
Tubing material	Main tubing: DEHP free polyvinyl Chloride (PVC)
Set change instruction	Change the set segment at least every 24hrs. Change the whole set according to local guidance
Packaging	Individual sealed pouch (ea). 300 ea/box (6 inner cases of 50ea)
Labelling languages	English, Estonian, Portuguese, Russian, Turkish
Sterilization	Ethylene Oxide (EtO)
Shelf life	3 years from date of manufacture. See pouch for applicable expiry date
Additional information	Single patient use, do not re-sterilize. Do not Re-use. Non-pyrogenic
Presence of product of animal or biological origin	No
Legal Manufacturer	Shinva Ande Healthcare Apparatus Co., Ltd. No.77 Development Zone North Road, New&Hi-Tech Zone, 255086 Zibo, Shangdong, China
Country of manufacture/origin	China
CE and Authorized Representative	MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany CE 0123
Quality system	ISO13485 TÜV SÜD Product Service GmbH