Technical Data Sheet

Product specification

1. Product name	SOL-VET™ Insulin Syringe with Fixed Needle
2. Description	The SOL-VET™ Insulin Syringe with Fixed Needle is used to inject insulin into the body.
3. Indication for use	Insulin Syringe is used to inject insulin into the animal's body.
4. Intended use	The Insulin Syringe is used to inject insulin into the body. Not for human use.
5. Intended users	Veterinary professionals and pet owners
6. Instructions for Use	N/A
7. Warning and precautions	Cautions: • Single-use device. Re-use or use if the package is damaged may lead to infection or other illness/ injury.
8. Storage information	Keep dry, Keep away from sunlight, Storage condition: Temperature: 0°C ~ 40°C, Humidity: ≤ 80%
9. Sizes and REF numbers	

REF	Product Description
V1305	1ml U-100 Insulin Syringe with Fixed Needle 30G*1/2 (PE Bag)
V12905	1ml U-100 Insulin Syringe with Fixed Needle 29G*1/2 (PE Bag)
V530516	0.5ml U-100 Insulin Syringe with 1/2 unit markings 30G*5/16 (PE Bag)
V5305	0.5ml U-100 Insulin Syringe with 1/2 unit markings 30G*1/2 (PE Bag)
V5295	0.5ml U-100 Insulin Syringe with 1/2 unit markings 29G*1/2 (PE Bag)
V3305	0.3ml U-100 Insulin Syringe with 1/2 unit markings 30G*1/2 (PE Bag)

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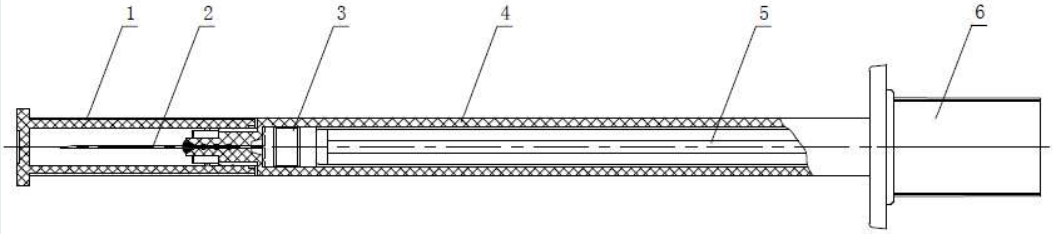
V3295	0.3ml U-100 Insulin Syringe with 1/2 unit markings 29G*1/2 (PE Bag)
V30516	0.3ml U-100 Insulin Syringe with 1/2 unit markings 30G*5/16 (PE Bag)
V1305-40	1ml U-40 Insulin Syringe with Fixed Needle 30G*1/2 (PE Bag)
V12905-40	1ml U-40 Insulin Syringe with Fixed Needle 29G*1/2 (PE Bag)
V5305-40	0.5ml U-40 Insulin Syringe with 1/2 unit markings 30G*1/2 (PE Bag)
V530516-40	0.5ml U-40 Insulin Syringe with 1/2 unit markings 30G*5/16 (PE Bag)
V5295-40	0.5ml U-40 Insulin Syringe with 1/2 unit markings 29G*1/2 (PE Bag)
V3305-40	0.3ml U-40 Insulin Syringe with 1/2 unit markings 30G*1/2 (PE Bag)
V32905-40	0.3ml U-40 Insulin Syringe with 1/2 unit markings 29G*1/2 (PE Bag)
V30516-40	0.3ml U-40 Insulin Syringe with 1/2 unit markings 30G*5/16 (PE Bag)

Technical information

1. List of materials	Component name	Material
	Needle cap	Polypropylene
	Cannula	Stainless steel: SUS304
	Gasket	Latex free rubber
	Barrel	Polypropylene
	Plunger	Polypropylene
	Protective cap	Polypropylene
	Adhesive	UV glue
	Needle Lubricant	Silicon oil
	Barrel Lubricant	Silicon oil
2. Latex free	YES	
3. PHT / DEHP / BPA free	YES	
4. Materials of concern	Not contain substances in a concentration that is above 0.1% w/w referred to following: • Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament.	

		• Endocrine-disrupting substances identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (SVHC) or once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council in accordance with the criteria that are relevant to human health amongst the criteria established therein.	
5. Shelf life		5 years	
6. Sterilization method		Sterilized with Ethylene Oxide	
7. Packaging specification	7.1 Sales unit	10 units	Units per pe bag
		100 units (10 pe bags)	Units per box (PE bags per box)
		1000 units (10 boxes)	Units per case (Boxes per case)

8. Technical Drawing



1. Needle cap
2. Cannula
3. Gasket
4. Barrel
5. Plunger
6. Protective cap

Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485	
2. Product classification	Veterinary medical devices	
3. List of standards	**The product is compliant with the following standards and regulations:**	
	Document reference	**Title**
	ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
	ISO 7864:2016	Sterile hypodermic needles for single use -- Requirements and test methods

	ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	ISO 10993-4:2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
	ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	ISO 10993-7:2008 ISO 10993-7:2008/Amd 1:2019	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	ISO 10993-10:2023	Biological evaluation of medical devices -- Part 10: Tests for skin sensitization
	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
	ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	ISO 11737-1 :2018 ISO 11737-1:2018/Amd 1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
	ISO 11737-2:2019	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
	ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
	ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
	ISO 11607-1:2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ISO 11607-2:2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
	ISO 11135:2014 ISO 11135-1:2014/Amd 1:2018	Sterilization of healthcare products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices -- Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/DAmd 1:2018)
	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

	ISTA 3A 2018	General Simulation Performance Tests, Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated)
	ISO 780: 2015	Packaging -- Distribution packaging -- Graphical symbols for handling and storage of packages
	ASTM F2825-18	Standard Practice For Climatic Stressing Of Packaging Systems For Single Parcel Delivery

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REV	02	Date	2023.08.28

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