Aiguilles conventionelles KDL®

Description:

Aiguilles stériles pour prélèvement multiple de sang veineux pour un usage en médicine humaine par des professionnels de santé habilités.

Facilite de Manipulation:

- Manchon souple sur l'aiguille perce bouchon
- Surfaces de préhension plates et non polies sur les capuchons protecteurs

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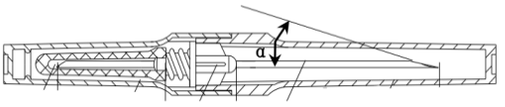


Caractéristiques Generales

Materiaux	• Capuchon aiguille perce-bouchon	Polyéthylène
	• Manchon	Elastomère de synthèse
	• Capuchon aiguille I.V	Polypropylène (PP)
	• Aiguille de prélèvement	Acier inoxydable grade 304
	• Aiguille perce-bouchon	Acier inoxydable
	• Embase	ABS
Fabricant	Zhejiang Kindly Medical Device Certification ISO 13485:2016 par le TUV SUD No Q50363360056	
Pays d'origine	Chine	
Rep. Europeen	Shanghai International Holding Corp. GmbH (Europe)	
Marquage CE	Dispositif Médical – Classe II Directive européenne 93/42/CEE Certificat de conformité de marquage CE n° G1 0336336 0054 délivré par le TUV SÜD, n° d'organisme 0123. Certificat disponible sur demande	
Stérilité	10-6 SAL (SAL = Sterility Assurance Level = Niveau d'Assurance de Stérilité) Procédé de stérilisation : oxyde d'éthylène conforme à la norme internationale EN ISO 11135.	
Conservation	Durée de vie du produit (dans l'emballage d'origine) : 5 ans Température: Tenir à l'abri des rayons solaires	

Produit Apyrogène: Oui
Présence de Latex : Non
Présence de DNR (caoutchouc naturel sec) :Non
Présence de Phtalates :Non
Présence de produits d'origine animale :Non

Caractéristiques spécifiques

Références Metze	KD0120G25	KD0120G38	KD0121G25	KD0121G38	KD0122G25	KD0122G38
Dimension de l'aiguille: Longueur (mm) x diamètre externe (mm, G)	25x9/10 (20G)	38x9/10 (20G)	25x8/10 (21G)	38x8/10 (21G)	25x7/10 (22G)	38x7/10 (22G)
Couleur	Jaune		Vert		Noir	

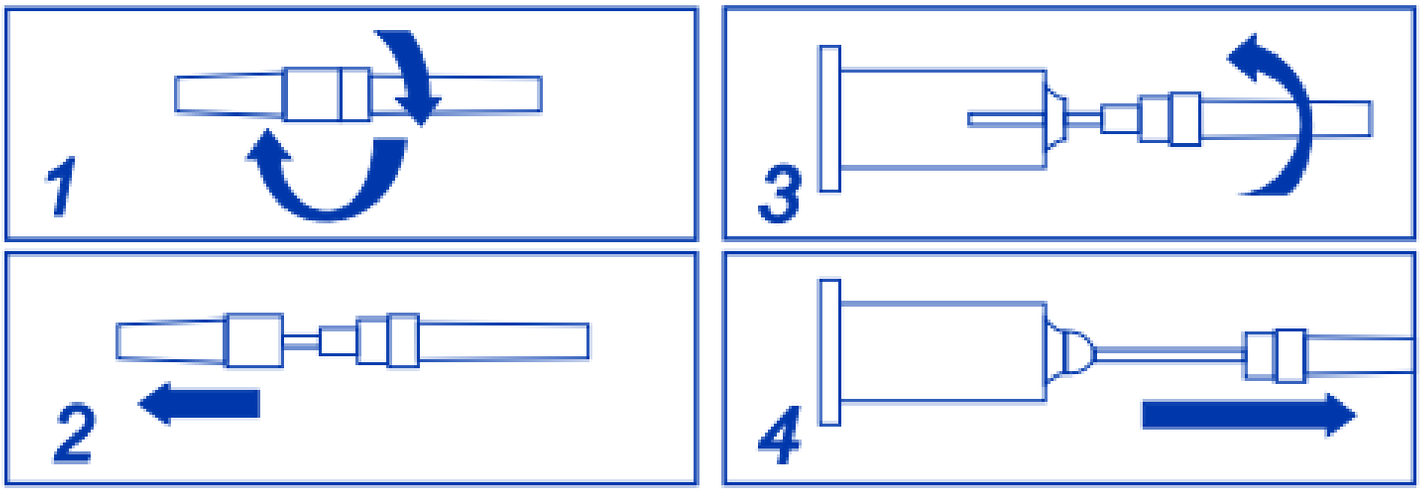
Fiche technique

Aiguilles conventionelles

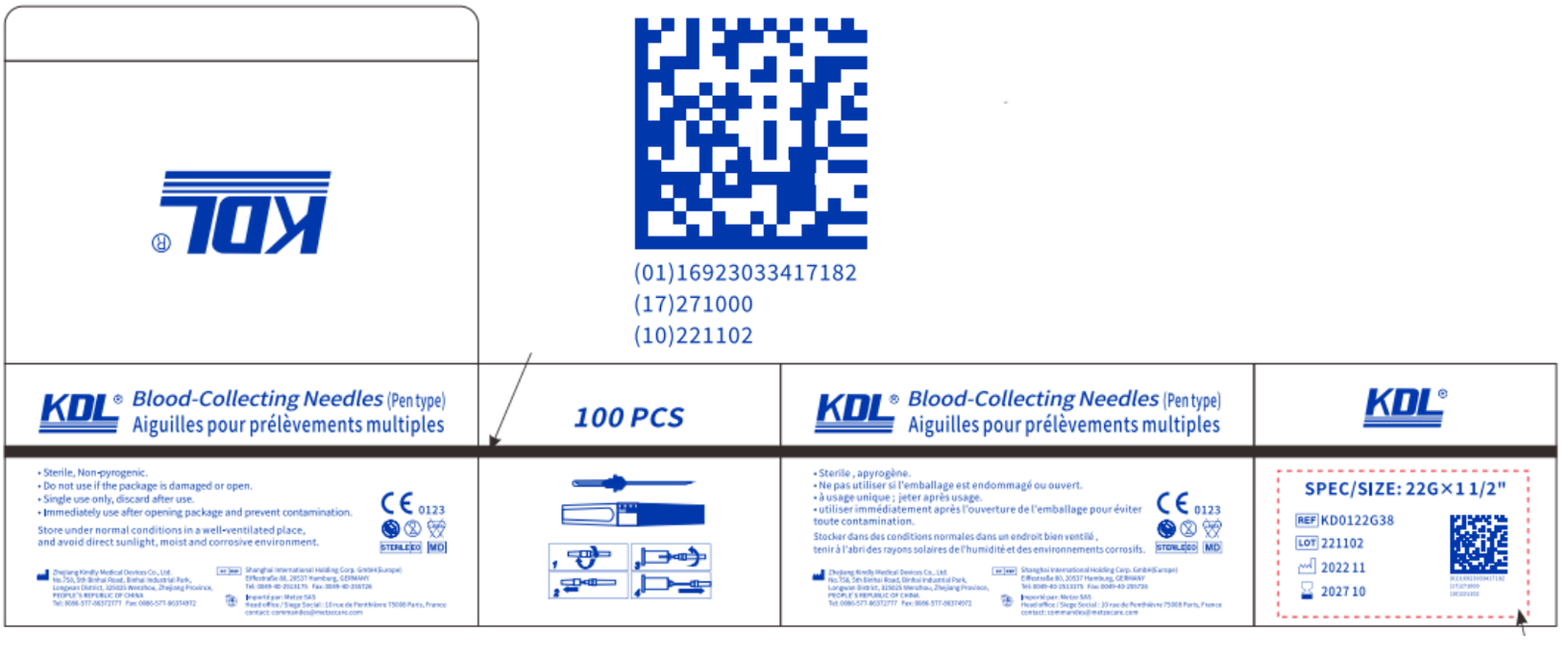
Conditionnement et emballage

Conditionnement detaille	
Boîte cartonnée 100 pcs	Master Carton 50 boites (50*100pcs)
130*83*72mm	44*28*41cm 13.2 kgs

Recommendation d'utilisation



Etiquetage & UDI:



Importé & Distribué par: Metze SAS
10 rue de Penthièvre, 75008 Paris
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01 88 61 13 86

Normes appliquées

Les normes appliquées dans la conception, la fabrication, l'emballage et l'étiquetage des lignes de produits des unités de prélèvement sécurisées sont énumérées dans le tableau suivant.

Normes / Réglementation	Description
EN 556-1:2001/ AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices
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
ISO10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993- 7:2008/AC:2009	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
ISO10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
ISO 11135:2014	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-2:2015	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product
ISO 13485:2016	Medical Devices – Quality management system – Requirements for regulatory purposes
ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
ISO 14644-1:2015	Cleanrooms and Associated Controlled Environments Part 1: Classification and Air Cleanliness
ISO 14644-2:2015	Cleanrooms and Associated Controlled Environments Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2005	Cleanrooms and associated controlled environments —Part 3: Test methods
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN ISO 14971: 2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates
EN 62366:2008+A1:2015	Medical devices - Application of usability engineering to medical devices
ASTM F1980:2016	Standard guide for accelerated aging of sterile barrier systems for medical device