I.V Néo natale - Microperfuseur Mono-Ailette

Description :

Microperfuseur Mono-Ailette, stériles, à usage unique, avec tubulure de 300mm, adaptateur Luer-lock.

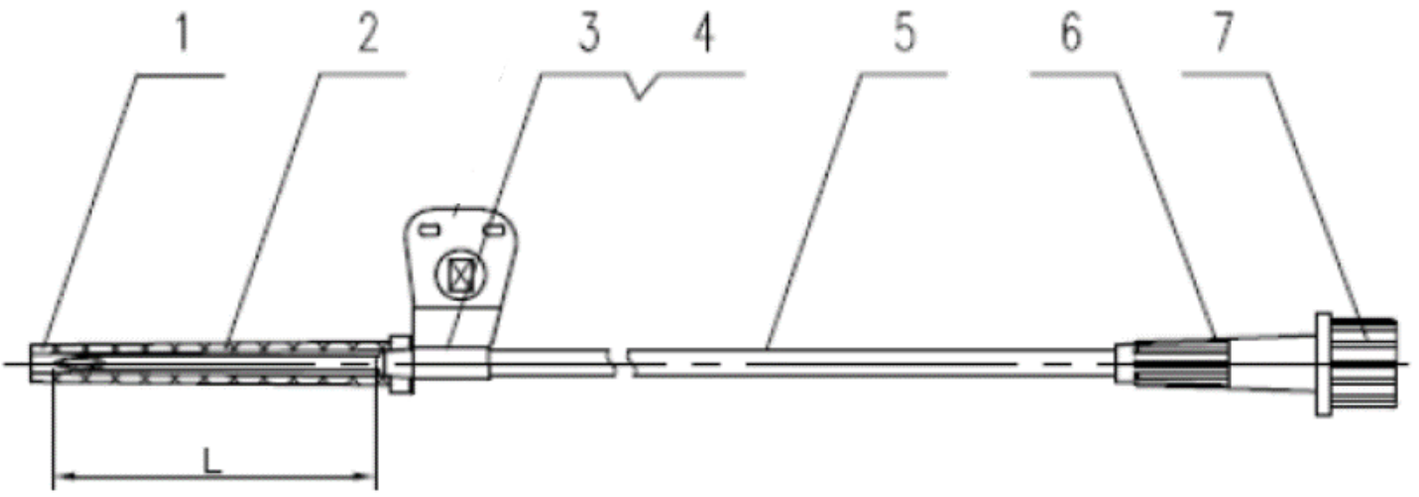
Indication:

Aiguille épicrânienne pour thérapie intraveineuse par ponction et mise en place du dispositif sur les veines superficielles du nouveau-né et du nourrisson.

Fiche technique

Microperfuseur Mono-Ailette

Caractéristiques Generales



Materiaux	1. Capuchon aiguille I.V	Polypropylène (PP)
	2. Aiguille de prélèvement	Acier inoxydable grade 304
	3. Ailette	PVC (sans DEHP)
	4. Embase Aiguille	ABS [poly (acrylonitrile, butadène, styrène)]
	5. Tubulure	PVC (sans DEHP)
	6. Cône Luer Lock femelle	ABS [poly (acrylonitrile, butadène, styrène)]
	7. Capuchon Luer lock Male	Polypropylène (PP)
Pays d'origine	Chine	
Rep. Europeen	Shanghai International Holding Corp. GmbH (Europe)	
Marquage CE	Dispositif Médical – Classe IIb selon MDR 745/2017 Annex IX Certificat de conformité de marquage CE n° G100363360058 délivré par le TUV SÜD, n° d'organisme 0123.	
UDI EMDN GMDN	UDI : 69230334202002b00301M8 UMDNS : 12-752 GMDN : 17-825	
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	

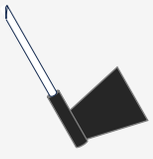
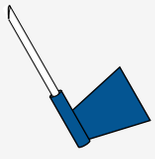
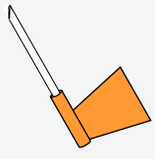
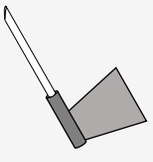
Produit Apyrogène: Oui
Présence de Latex : Non
Présence de DNR (caoutchouc naturel sec) :Non
Présence de Phtalates :Non
Présence de produits d'origine animale :Non

Fiche technique
Microperfuseur Mono-Ailette

EU-MDR 2017/745

Metze care

Caractéristiques spécifiques

Références Metze	MPS22300KD	MPS23300KD	MPS25300KD	MPS27300KD
Dimensions aiguille (Ø externe x Longueur)	22G x 3/4" (0.7mm x 19mm)	23G x 3/4" (0.6mm x 19mm)	25G x 3/4" (0.5mm x 19mm)	27G x 3/4" (0.4mm x 19mm)
Longueur Tubulure	300mm			
Embout luer Lock	Avec			
Bouchon Protecteur embout	Avec			
Couleur				

Conditionnement et emballage

Conditionnement detaillé		
Emballage individuel	Boite 100 pcs	Master Carton 20 boites (20*100pcs) 2000 pcs / carton
Pouch papier plastique	240*175*85	50x37.5*46cm 6.2 kgs

Importé & Distribué par: Metze SAS
10 rue de Penthièvre, 75008 Paris
commandes@metzecare.com
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 ISO 23908: 2013	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
MEDDEV.2.7.1 Rev.4	Clinical evaluation: A Guide for manufacturers and notified bodies
EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2018)
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
EN ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2015)
EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016) sections complied with: 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.13, 4.15.2
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods (ISO 9626:2016)
EN ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification (ISO 6009:2016)
EN 20594-1：1993/AC:1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN 1707：1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
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
EN 62366-1:2015/A1 2020	Medical devices - Part 1: Application of usability engineering to medical devices
IEC TR 62366-2:2016	Medical devices — Part 2: Guidance on the application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 15223-2: 2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices
EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates
EN ISO 11135:2014/A1:2019	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018 /A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: termination of a population of microorganisms on products
EN ISO 11737-2:2020	Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

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 ISO 11138-1:2017	Sterilization of health care products -- Biological indicators - Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 13485:2016/A11:2021	Medical Devices – Quality management system – Requirements for regulatory purposes
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Bio contamination control -- Part 1: General principles and methods
EN ISO 14644-1:2015	Cleanrooms and Associated Controlled Environments Part 1: Classification and Air Cleanliness
EN ISO 14644-2:2015	Cleanrooms and Associated Controlled Environments Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments —Part 3: Test methods
EN ISO 14971:2019/A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2018	Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
EN ISO10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2017	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2023	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
ASTM F1980:2021	Standard guide for accelerated aging of sterile barrier systems for medical device
ISO 2859-1:1999	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspectionS
AAMI TIR28:2016	Product adoption and process equivalence for ethylene oxide sterilization