Technical Specification Datasheet –

Customer Certification of the finished Device

	Manufacturer: **PAJUNK® GmbH Medizintechnologie** Karl-Hall-Strasse 1 78187 Geisingen Germany	Distributor: *[Authorized Stamp here]*
	Manufactured according to ISO13485, ISO14971, GMP	
	The product and manufacturing process is free of Latex.	
	Project	R20-0617
	Device	Spike
		Trade name: Spike Generic name: Elastomeric infusion pump system
	Custom-made	No
	Regulatory Information	Regulation 2017/745 (MDR) class Is, rule 2 GMDN: 46542 Elastomeric infusion pump system
	Basic-UDI-DI	4048223-R20-0617DJ
	EC Certificate	51268-60-02-00
	Notified Body	DEKRA Certification GmbH, Stuttgart; NBC: 0124
	Item codes	Please refer to the corresponding Declaration of Conformity R20-0617
	Device Description	The Spike subject to this file are accessories for the Elastomeric Pump. The Spike are marketed as a set component within sterile procedure trays and FuserPump Set (coming with elastomeric pump, cannula/s catheters/s, syringe, etc.) as well as individually packed sterile
	Intended Use	For filling the FuserPump.
	Patient population	Not restricted

	Procedure	1. Check the packing for damage. If the packing is damaged, then the product may not be used any more. 2. Remove the product from its packing. 3. Check the product for damage. A damaged product may not be used any further. 4. When using products of other manufacturers as supplementary components, make sure that the products are compatible. 5. When initiating the administration of the pre-, intra- and post operative medication, proceed in accordance with current medical standards and according to the rules of good clinical practice.	
	Picture (not for scale)		
	Compatibility	LUER connector according ISO 80369-7	
	Materials	Spike: ABS Locking Cap: PE	
	Packaging	**Single device:**	Tyvek / PE foil Heat sealed
		Multiple Units:	Card board box
	Additional information		Non-pyrogenic
			Does not contain latex
			Does not contain Phthalates
☒	Biocompatibility	Proven biocompatibility according to FDA modified ISO10993-1: (short-term, invasive patient contact) for all relevant parts.	

PAJUNK® GmbH
Medizintechnologie
Karl-Hall-Straße 1
78187 Geisingen
Germany

info@pajunk.com
pajunk.com
Tel.: +49 7704 9291-0
Fax: +49 7704 9291-600

USt-IdNr.: DE 812493272
Sitz der Gesellschaft: Geisingen
Registergericht: Stuttgart HRB 450245
Geschäftsführung:
Simone Pajunk-Schelling, Martin Hauger

Bank:
Volksbank eG Villingen *IBAN:* DE14 6949 0000 0080 0577 09 | *BIC:* GENODE61VS1
Deutsche Bank Villingen-Schwenningen *IBAN:* DE72 6928 0035 0832 9333 00 | *BIC:* DEUTDE6F694
Commerzbank AG *IBAN:* DE72 6928 0035 0832 9333 00 | *BIC:* DRESDEFF692

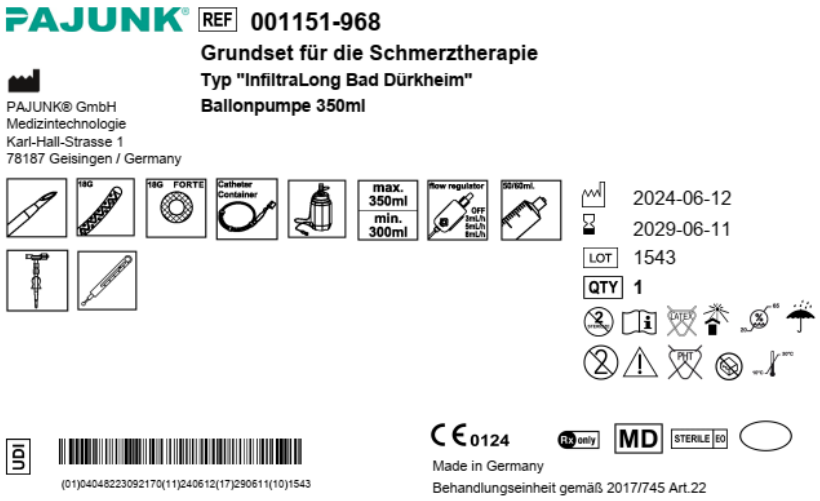
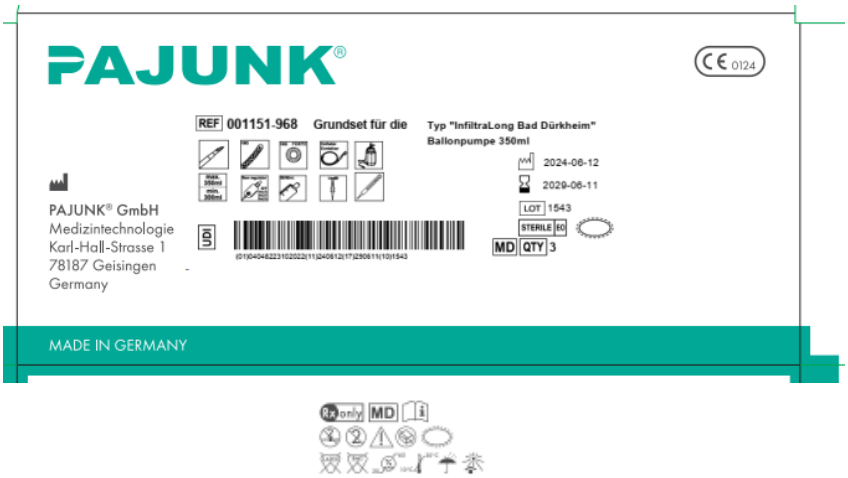
☒	Sterility	STERILE EO	SAL 10^{-6}, validated process, regular tests per product Sterilized with: ☒ EtO ☐ Gamma
☒	Shelflife (sterility and performance)		60 month from manufacturing, Label imprint. 5 years
☒	Further Imprints		Indicates Date of Manufacturing
		LOT	Indicates Lot - by consecutive numbering per sterile batch
☐	Re-Sterilization	Not applicable	
☐	Maintenance	Not applicable	
☒	Special Attention		Carefully read Instructions for use!
			Do not use if product or packaging is damaged
			Keep away from sunlight
			Keep away from rain
			Disposable! Do not re-sterilize! Re-use may harm patient!
			Disposable! Do not re-use! Re-use may harm patient!
			Storage: Temperature Range 20 ±10 °C
			Storage: Humidity Range 20-65%

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	Label sample/ Marking patterns	
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Released/Update	June 05th 2024	
		Christian Quass, Director Regulatory Affairs, June 05th 2024

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