

KONFORMITÄTSERKLÄRUNG GEMÄß (EU)
2017/745

Wir,	PAJUNK® GmbH Medizintechnologie Karl-Hall-Str. 1, 78187 Geisingen, Baden-Württemberg, Germany, Ein-eindeutige Registrierungsnummer Hersteller (SRN): DE-MF-000005510		
erklären in alleiniger Verantwortung als Hersteller des Produkts, dass das Medizinprodukt			
Typ	Siehe Anhang		
Annex VIII, 2017-745-EU	Klasse IIa		
Zweckbestimmung	Zugang zu und Injektionen in periphere Nerven, manchmal unter Anwendung von Nervenstimulationstechniken		
EMDN-Code	A010302		
GMDN	61546		
PAJUNK®-No.	R20-0089; R20-0090; R20-0091; R20-0092		
Basic-UDI-DI	4048223-R20-0089DD; 4048223-R20-0090CW; 4048223-R20-0091CY; 4048223-R20-0092D2		
alle Anforderungen der Verordnung (EU) 2017/745 erfüllt.			
Common Specifications	n.a.	n.a.	
Andere einschlägige Rechtsvorschriften der Union, die die Ausstellung einer EU-Konformitätserklärung vorsehen (nicht im Rahmen der Überprüfung durch die benannte Stelle)	n.a.		
Zertifikat	(EU)2017/745 Annex IX Chapter I und Chapter III	51268-60-04	2025-04-30 – 2030-02-18

Benannte Stelle

DEKRA Certification GmbH, Notified Body code: 0124

Handwerkstraße 15, 70565 Stuttgart

Konformitätsbewertungsverfahren

☒ **(EU)2017/745 Annex IX Chapter I und Chapter III**

☐ **ohne NB 0124**

Geisingen, 2025-06-17

date/ place

Christian G. H. Quaß, Director Regulatory Affairs, Safety Officer Responsible Person –
Regulatory (Person responsible for regulatory compliance, Art. 15 b-d)
name and function

Revision History

Version	Date of first Issuance	Author(s)	Subject of revision
1	2022-11-11	CQ	New certificate (51268-60-01 Annex Rev 1)
2	2023-07-24	CQ	New certificate (51268-60-01 Annex Rev 2)
3	2023-12-22	PAW	New certificate (51268-60-02-00)
4	2024-09-09	PAW	New certificate (51268-60-02-01)
5	2024-12-23	PAW	New certificate (51268-60-02-02); Combining variants
6	2025-02-17	PAW	New certificate (51268-60-03-00)
7	2025-02-19	PAW	New certificate (51268-60-03-01); Discontinued item codes: 001246-71; 001246-74; 001247-85; 001246-31H; 001156-87; 001156-73; 001157-88; 001157-70F; 001156-29G
8	2025-04-30	PAW	New certificate (51268-60-04)
9	2025-06-11	PAW	Fault in Revision 7: Item codes 001246-71 and 001246-74 were not discontinued.

Anhang R20-0089-102024_DE.docx

Artikel, für die diese Konformitätserklärung gilt (R20-0089-102024_DE.docx)

Item code	Basic UDI-DI	Specification
001246-72	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 20G (0,9) Length: 120mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-76	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 20G (0,9) Length: 150mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-77	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 21G (0,8) Length: 100mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-82	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 120mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-74	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 50mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-71	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 80mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable

Item code	Basic UDI-DI	Specification
001247-76	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 20G (0,9) Length: 150mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-77	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 21G (0,8) Length: 100mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-74	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 50mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-71	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 80mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-75	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 24G (0,55) Length: 30mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-80	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 35mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-80	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 35mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable

Item code	Basic UDI-DI	Specification
001246-81	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 50mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-81	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 50mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-31G	4048223-R20-0090CW	UniPlex II NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 50mm Distal end: SPROTTE® type Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-31J	4048223-R20-0090CW	UniPlex II NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 90mm Distal end: SPROTTE® type Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001156-72	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 20G (0,9mm) Length: 120mm (4 3/4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-76	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 20G (0,9mm) Length: 150mm Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-77	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 21G (0,8mm) Length: 100mm (4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable

Item code	Basic UDI-DI	Specification
001156-82	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 120mm (4 3/4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001157-77	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 21G (0,8mm) Length: 100mm (4") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-84	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 100mm (4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-74	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 50mm (2") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001157-74	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 50mm (2") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-71	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 80mm (3 1/4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001157-71	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 80mm (3 1/4") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable

**KONFORMITÄTSERKLÄRUNG GEMÄß (EU)
2017/745 - ANHANG**

Item code	Basic UDI-DI	Specification
001157-81	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 24G (0,55mm) Length: 50mm (2") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-80	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 25G (0,5mm) Length: 35mm (1 3/8") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-81	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 25G (0,5mm) Length: 50mm (2") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-31H	4048223-R20-0092D2	UniPlex® NanoLine® Cannula/ Needle Diameter 22G (0,7mm) Length: 70mm (2 3/4") Distal end: SPROTTE® style Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-31G	4048223-R20-0092D2	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 50mm (2") Distal end: SPROTTE® style Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable

Geisingen, 2025-06-17

place, date

Christian G. H. Quaß, Director Regulatory Affairs, Safety Officer
Person Responsible for Regulatory Compliance – Regulatory Affairs (PRRC-RA)
name and function

ANNEX-PN1556b

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DECLARATION OF CONFORMITY WITH (EU) 2017/745



We,	PAJUNK® GmbH Medizintechnologie Karl-Hall-Str. 1, 78187 Geisingen, Baden-Württemberg, Germany, Single Registration Number (SRN): DE-MF-000005510		
declare on our sole responsibility in the economic operator role as the manufacturer of the device that the medical device			
Type	Refer to annex		
Annex VIII, 2017-745-EU	Class IIa		
Intended Purpose	Access and injections to peripheral nerves, sometimes using nerve stimulation techniques		
EMDN-Code	A010302		
GMDN	61546		
PAJUNK®-No.	R20-0089; R20-0090; R20-0091; R20-0092		
Basic-UDI-DI	4048223-R20-0089DD; 4048223-R20-0090CW; 4048223-R20-0091CY; 4048223-R20-0092D2		
meets all the provisions of the (EU) 2017/745.			
Common Specifications	n.a.	n.a.	
Other relevant Union legislation that provides for the issuing of an EU declaration of conformity (not within scope of Notified Body Review)	n.a.		
Certificate	(EU)2017/745 Annex IX Chapter I and Chapter III	51268-60-04	2025-04-30 – 2030-02-18

Notified body

DEKRA Certification GmbH, Notified Body code: 0124

Handwerkstraße 15, 70565 Stuttgart

Conformity assessment procedure

☒ **(EU)2017/745 Annex IX Chapter I and Chapter III**

☐ without NB 0124

Geisingen, 2025-06-17

date/ place

Christian G. H. Quaß, Director Regulatory Affairs, Safety Officer Responsible Person –
Regulatory (Person responsible for regulatory compliance, Art. 15 b-d)
name and function

DECLARATION OF CONFORMITY WITH (EU) 2017/745



Revision History

Version	Date of first Issuance	Author(s)	Subject of revision
1	2022-11-11	CQ	New certificate (51268-60-01 Annex Rev 1)
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**DECLARATION OF CONFORMITY WITH
(EU) 2017/745 - ANNEX**



Annex R20-0089-102024_EN.docx

Items covered by this declaration of conformity (R20-0089-102024_EN.docx)

Item code	Basic UDI-DI	Specification
001246-72	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 20G (0,9) Length: 120mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-76	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 20G (0,9) Length: 150mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-77	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 21G (0,8) Length: 100mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-82	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 120mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-74	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 50mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-71	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 80mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable

**DECLARATION OF CONFORMITY WITH
(EU) 2017/745 - ANNEX**

Item code	Basic UDI-DI	Specification
001247-76	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 20G (0,9) Length: 150mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-77	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 21G (0,8) Length: 100mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-74	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 50mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-71	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 80mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-75	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 24G (0,55) Length: 30mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-80	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 35mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-80	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 35mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable

**DECLARATION OF CONFORMITY WITH
(EU) 2017/745 - ANNEX**

Item code	Basic UDI-DI	Specification
001246-81	4048223-R20-0089DD	UniPlex II Facet NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 50mm Distal end: Facet Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001247-81	4048223-R20-0089DD	UniPlex II Facet S NRFit® Cannula/ Needle Diameter: 25G (0,5) Length: 50mm Distal end: Facet-S Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-31G	4048223-R20-0090CW	UniPlex II NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 50mm Distal end: SPROTTE® type Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001246-31J	4048223-R20-0090CW	UniPlex II NRFit® Cannula/ Needle Diameter: 22G (0,7) Length: 90mm Distal end: SPROTTE® type Coating: NanoLine Parylene Proximal end/ hub: ISO 80369-6 NRFit® Injection tube Connection cable
001156-72	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 20G (0,9mm) Length: 120mm (4 3/4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-76	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 20G (0,9mm) Length: 150mm Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-77	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 21G (0,8mm) Length: 100mm (4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable

**DECLARATION OF CONFORMITY WITH
(EU) 2017/745 - ANNEX**

Item code	Basic UDI-DI	Specification
001156-82	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 120mm (4 3/4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001157-77	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 21G (0,8mm) Length: 100mm (4") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-84	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 100mm (4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-74	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 50mm (2") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001157-74	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 50mm (2") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-71	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 80mm (3 1/4") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001157-71	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 80mm (3 1/4") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable

**DECLARATION OF CONFORMITY WITH
(EU) 2017/745 - ANNEX**

Item code	Basic UDI-DI	Specification
001157-81	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 24G (0,55mm) Length: 50mm (2") Distal end: Facet-S Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-80	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 25G (0,5mm) Length: 35mm (1 3-8") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-81	4048223-R20-0091CY	UniPlex® NanoLine® Cannula/ Needle Diameter: 25G (0,5mm) Length: 50mm (2") Distal end: Facet Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-31H	4048223-R20-0092D2	UniPlex® NanoLine® Cannula/ Needle Diameter 22G (0,7mm) Length: 70mm (2 3-4") Distal end: SPROTTE® style Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable
001156-31G	4048223-R20-0092D2	UniPlex® NanoLine® Cannula/ Needle Diameter: 22G (0,7mm) Length: 50mm (2") Distal end: SPROTTE® style Coating: NanoLine® Parylene Proximal end/ Hub: ISO 80369-7 LUER Injection Tube Connection Cable

Geisingen, 2025-06-17

place, date

Christian G. H. Quaß, Director Regulatory Affairs, Safety Officer
Person Responsible for Regulatory Compliance – Regulatory Affairs (PRRC-RA)
name and function

ANNEX-PN1556b

R20-0089-102024_EN.docx

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EU Certificate

for the assessment of the
quality management system



according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the
manufacturer

PAJUNK GmbH Medizintechnologie

Single Registration Number (SRN): DE-MF-000005510

Karl-Hall-Straße 1, 78187, Geisingen, Deutschland

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo51268-01 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51268-60-04

Certificate valid from:

2025-04-30

Certificate valid to:

2030-02-18

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-092

EU Certificate no. 51268-60-04

Following devices/device categories are included in this certificate:

Sterilized Procedure Packs according to article 22(3) of MDR (EU) 2017/745:

Applicable Single Registration Number (SRN): DE-PR-000019405

MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Brand / Variants / item code group
MDN 1201	T0202	Surgical procedural kits (excluding surgical instrument kits)	Basisset Basisset NRFit® Grundset Grundset NRFit® Basics set Customized Convenience Kit Customized Convenience Kit NRFit®
MDN 1201	A010302	Plexus block needles and kits	Grundset Grundset NRFit® Customized Convenience Kit Customized Convenience Kit NRFit®
MDN 1201	N010401	Peripheral nervous system catheters and kits	Grundset Grundset NRFit® Customized Convenience Kit Customized Convenience Kit NRFit®
MDN 1201	A060203	Pleural drainages with valve and kits	Grundset Sicherheits - Pleurapunktionsset Customized Convenience Kit
MDN 1201	A01020201	Iliac-sternal biopsy needles and kits	Grundset Customized Convenience Kit
MDN 1201	A01020199	Needles and kits for histological and cytological biopsy of soft tissues – other	Grundset Customized Convenience Kit
MDN 1201	A010599	Ophthalmology injection needles and kits - other	Grundset Customized Convenience Kit
MDN 1201	A01030101	Needles and kits - spinal anaesthesia	Grundset Grundset NRFit® Customized Convenience Kit Customized Convenience Kit NRFit® IntraLong IntraLong NRFit® SPROTTE® NRFit® Kit
MDN 1201	A019014	Lumbar puncture needles and kits	Grundset Grundset NRFit® Customized Procedure Kit NRFit®
MDN 1201	A01030102	Needles and kits-peridural anaesthesia	EpiLong NRFit® EpiLong EpiLong I EpiLong Soft

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MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Brand / Variants / item code group
			EpiLong Soft Sono EpiLong Tuohy VPC EpiLong I Tuohy VPC EpiLong Soft VPC EpiLong Paed EpiLong Echo Paed EpiLong Paed NRFit® EpiLong Echo Paed NRFit® EpiLong Echo Pead NRFit® EpiLong Soft NRFit® EpiLong II EpiLong II Soft EpiLong II VPC EpiLong II NRFit® EpiLong II Soft NRFit®
MDN 1201	A0103010	Epidural anaesthesia needles and kits	Grundset Grundset NRFit® Customized Convenience Kit Customized Convenience Kit NRFit® CauDal NRFit® kit
MDN 1201	A01030103	Combined epidural and spinal anaesthesia needles and kits	Grundset Grundset NRFit® EpiSpin Lock EpiSpin Lock Soft EpiSpin Safety NRFit® EpiSpin II Safety EpiSpin II EpiSpin Lock Soft VPC EpiSpin NRFit® EpiSpin Soft NRFit®

Class Is

For the devices listed below, the review of the quality management system refers exclusively to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Brand / Variants / item code group
Sterile devices			
MDN 1201	A018099	Needles - other Accessories /	Retaining Plate/ Wings
MDA 0305	Z120622	Transcutaneous electrical nerve stimulators	StimuLong cable/ Extension cable MultiStim cable/ Extension cable
MDN 1201	N02010180	Peridural / epidural spinal catheters and kits - accessories	Insertion Aid FixoLong FixoCath

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MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Brand / Variants / item code group
			FixoLong NRFit®
MDN 1201	Z12050201	Extracorporeal perfusion pump	FuserPump Filler FuserPump Filler NRFit® Spike Spike NRFit®
MDN 1201	Z12109003	Cerebrospinal fluid pressure monitoring systems	Spinal Manometer Spinal Manometer NRFit® Spinal Manometer/ Manometer Extension
MDN 1201	A030104	Flow Regulators	NerveGuard NerveGuard NRFit®
MDN 1201	A020101	Loss-of-resistance syringes	VPC VPC NRFit® LOR LOR NRFit®
MDN 1201	A018044	Needle connectors and adapters	Fixation system EpiSpin (Lock) System
MDN 1201	A04010102	Aspiration and transfer filters (>= 5 microns)	Filter cannula NRFit®
MDN 1201	A030201	Extensions	Y-Tube Y-Tube NRFit® Injection tube Injection tube NRFit® Perfusorleitung NRFit®
MDN 1201	A0799	Adapters, connectors, ramps, stopcocks, caps - other	Locking cap Locking cap NRFit®
MDN 1201	A018002	Needle Guides	GCS

Class Ir

For the devices listed below, the review of the quality management system refers exclusively to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Brand / Variants / item code group
MDN 1208	L 0312	Trocars	TrocaObt HASSON TrocaObt PYRAMID TrocaObt CONE TrocaObt SHIELD TrocaObt PROTECT EcoBalloon OBT RA(-S) EcoBalloon OBT DIL EcoBalloon OBT SB EcoBalloon OBT PROTECT(-S)

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Shearing biopsy guns		
MDA 0312	Shearing biopsy guns/ DeltaCut	4048223-R20-1010CD
MDA 0312	Shearing biopsy guns/ PrimoCut	4048223-R20-1013CK
MDA 0312	Shearing biopsy guns/ CoreCut	4048223-R20-1015CP
Adapters, connectors, ramps, stopcocks, caps - other		
Connection option for a catheter without a hub		
MDN 1201	Adapters, connectors, ramps, stopcocks, caps – other/ Clamping Adapter NRFit®	4048223-R20-0647DT
MDN 1201	StimuLong Clamping Adapter NRFit	4048223-R20-0648DV
MDN 1201	Adapters, connectors, ramps, stopcocks, caps – other// Clamping Adapter	4048223-R20-0649DX
MDN 1201	Clamping Adapter Catheter connector/ adapter, clamping, colour coded, Stimulation, LUER	4048223-R20-0650DG
Interconnect/ convert NRFit®		
MDN 1201	Adapter NRFit®	4048223-R20-0644DM
For directed routing of fluids in distal or proximal direction from one source to two (or more) different targets for injection/infusion or sampling.		
MDN 1201	Injection valve: 3-way stopcock NRFit®	4048223-R20-0744DS
Interconnect/ convert LUER and NRFit®		
MDN 1201	Injection valve: 2-way stopcock	4048223-R20-0746DW
Administration and collecting filters, Filtration of drugs dissolved in water, in order to protect patients from micro-organisms or micro-particles during the injection		
Filtration of drugs dissolved in water, in order to protect patients from micro-organisms or micro-particles during the injection.		
MDN 1201	Bacterial Filter/ Filter	4048223-R20-0657DW
MDN 1201	Bacterial Filter/ Filter NRFit®	4048223-R20-0659E2
Aspiration fine needles and kits, Extraction of soft tissue (e.g. soft tissue tumours), Medical removal of tissue or liquid for diagnostic purposes		
MDN 1201	Hypodermic needles - other / Chiba	4048223-R20-0843DV
MDN 1201	Hypodermic needles – other/ Initial Cannula	4048223-R20-1074D7
MDN 1201	Aspiration fine needles and kits/ Chiba	4048223-R20-1080D2

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
MDN 1201	Aspiration fine needles and kits/ Chiba	4048223-R20-1081D4
MDN 1201	Aspiration fine needles and kits/ Chiba Sono	4048223-R20-1090D5
Brachytherapy instruments To stabilise the tissue by puncturing the target area and extending the cannula hooks.		
MDN 1201	DeltaFix	4048223-R20-1115CU
Endotherapy, dissectors, single-use PAJUNK® balloon systems are intended for dilatation, as well as for fixation (structural balloon systems and ring-anchor balloon systems).		
MDN 1201	Endotherapy, dissectors, single-use/ EcoBalloon DIL	4048223-R20-2015CW
MDN 1201	Endotherapy, dissectors, single-use/ EcoBalloon DIL-XL	4048223-R20-2016CY
MDN 1201	Endotherapy, dissectors, single-use/ EcoBalloon DIL-BI	4048223-R20-2017D2
MDN 1201	Endotherapy, dissectors, single-use/ MonoBalloon DIL	4048223-R20-2029D9
MDN 1201	Endotherapy, dissectors, single-use/ MonoBalloon DIL-XL	4048223-R20-2030CS
MDN 1201	Endotherapy, dissectors, single-use/ MonoBalloon DIL-BI	4048223-R20-2031CU
Endotherapy, single-use surgical instrumentary – others PAJUNK® balloon systems are intended for dilatation, as well as for fixation (structural balloon systems and ring-anchor balloon systems).		
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ EcoBalloon SL EcoBalloon SL-S	4048223-R20-2019D6
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ EcoBalloon RA EcoBalloon RA-S	4048223-R20-2021CR
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ EcoBalloon URO EcoBalloon URO-S	4048223-R20-2022CT
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ EcoBalloon SB	4048223-R20-2024CX
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ MonoBalloon SL MonoBalloon SL-S	4048223-R20-2033CY
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ MonoBalloon RA MonoBalloon RA-S	4048223-R20-2035D4

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ MonoBalloon URO MonoBalloon URO-S	4048223-R20-2036D6
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ MonoBalloon SB	4048223-R20-2038DA
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ VarioBalloon SL Vario Balloon SL-S	4048223-R20-2046D9
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ VarioBalloon RA VarioBalloon RA-S	4048223-R20-2048DD
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ VarioBalloon URO VarioBalloon URO-S	4048223-R20-2049DF
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ VarioBalloon SB	4048223-R20-2051D2
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ VarioBalloon Duo	4048223-R20-2053D6
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ MonoBalloon Duo	4048223-R20-2054D8
MDN 1201	Endotherapy, single-use surgical instrumentary – others/ EcoBalloon Duo	4048223-R20-2055DA
Hypodermic needles - others		
MDN 1201	Hypodermic needles – others/ Split cannula	4048223-R20-0769EA
MDN 1201	Permanent cannula Subassembly; permanent cannula, teflon, bns	4048223-R20-0773DZ
MDN 1201	Hypodermic needles – others /Permanent cannula	4048223-R20-0774E3
MDN 1201	Permanent/ Inwelling cannula - PAJUNK needle/ Cannula: optional mandrin, LUER	4048223-R20-0775E3
MDN 1201	Hypodermic needles – others/ TunnEler Tunnelisator/ Awl needle/ cannula; trocar, bent	4048223-R20-0780DW
MDN 1201	Hypodermic needles – others/ TunnEler Tunneler Obturator; handle, split cannula	4048223-R20-0781DY
MDN 1201	Hypodermic needles – others/ GCS SPROTTE®	4048223-R20-0788EE

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Initial puncture; puncture to gain access for an anesthesia cannula		
MDN 1201	Hypodermic needles – others/ IntroDucer	4048223-R20-0826DV
MDN 1201	Hypodermic needles – others/ IntroDucer Sono	4048223-R20-0827DX
MDN 1201	Hypodermic needles – others/ IntroDucer 2.G	4048223-R20-0829E3
MDN 1201	Hypodermic needles – others/ IntroDucer NRFit®	4048223-R20-0830DL
MDN 1201	Hypodermic needles – others/ Pravaz cannula	4048223-R20-0835DW
MDN 1201	Hypodermic needles – others/ Dual Cannula System Initial cannula R20-1074	4048223-R20-1074D7
Injection		
MDN 1201	Injection cannula Cannula/ needle: Facet, Facet-S; Injection tube, LUER cannula R20-0833	4048223-R20-0833DS
MDN 1201	Injection cannula Cannula/ needle: Facet, Facet-S; Injection tube, NRFit	4048223-R20-0834DU
MDN 1201	Hypodermic needles – others/ Chiba R20-0843	4048223-R20-0843DV
MDN 1201	Hypodermic needles – others/ DeltaCut Coaxial sleeve	4048223-R20-1012CH
Injection of analgetic agents and contrast media for analgesia and diagnostics		
MDN 1201	Hypodermic needles – others/ Special puncture cannula acc. SPROTTE®	4048223-R20-1084DA
MDN 1201	Hypodermic needles – others/ PTC	4048223-R20-1085DC
MDN 1201	RGN Puncturing Needle System	4048223-R20-1086DE
I.V. cannulas – others		
Vascular puncture, if necessary placement of a guidance wire		
MDN 1201	I.V. cannulas – others/ VascularSono	4048223-R20-0816DS
Infusion and irrigation disposable syringes		
MDN 1201	Syringe Multi purpose, LUER, injection [LOCK, SLIP, 1ml - 50ml]	4048223-R20-0660DK
MDN 1201	Syringe NRFit® injection [LOCK, SLIP, 1ml - 50ml] ISO80369-6	4048223-R20-0662DP

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Needle and kits - Plexus block		
Access and injections to peripheral nerves, sometimes using ultrasound and/ or nerve stimulation techniques		
MDN 1201	Needle and kits - Plexus block/ UniPlex® II Facet NRFit®	4048223-R20-0089DD
MDN 1201	Needle and kits - Plexus block/ UniPlex® II NRFit®	4048223-R20-0090CW
MDN 1201	Needle and kits - Plexus block/ UniPlex® NanoLine® Cannula/ needle: Facet/ Facet-S, Stimulation cable, injection tube, NanoLine®, LUER	4048223-R20-0091CY
MDN 1201	Needle and kits - Plexus block/ UniPlex® NanoLine® Cannula/ needle: SPROTTE®, Stimulation cable, injection tube, NanoLine®, LUER	4048223-R20-0092D2
MDN 1201	Needle and kits - Plexus block/ SonoBlock Cannula/ needle: Facet/ Facet-S, CornerStone, NanoLine®, injection tube, LUER	4048223-R20-0107CN
MDN 1201	Needle and kits - Plexus block/ SonoBlock Cannula/ needle: SPROTTE, CornerStone, NanoLine®, injection tube, LUER	4048223-R20-0108CQ
MDN 1201	Needle and kits - Plexus block/ SonoBlock II Facet	4048223-R20-0112CF
MDN 1201	Needle and kits - Plexus block/ SonoBlock II Facet NRFit®	4048223-R20-0115CM
Access and injections to peripheral nerves, sometimes using ultrasound and/ or nerve stimulation techniques		
MDN 1201	Needle and kits - Plexus block/ SonoPlex® Stim Cannula/ needle: Facet/ Facet-S, CornerStone, Stimulation cable, injection tube, NanoLine®, LUER	4048223-R20-0117CR
MDN 1201	Needle and kits - Plexus block/ SonoPlex® Stim Cannula/ needle: SPROTTE, CornerStone, Stimulation cable, injection tube, NanoLine®, LUER	4048223-R20-0118CT
MDN 1201	Needle and kits - Plexus block/ SonoPlex® II Facet	4048223-R20-0119CV
MDN 1201	Needle and kits - Plexus block/ SonoPlex® II	4048223-R20-0120CE
MDN 1201	Needle and kits - Plexus block/ SonoPlex® II Facet NRFit®	4048223-R20-0124CN
MDN 1201	Needle and kits - Plexus block/ SonoPlex® II NRFit®	4048223-R20-0125CQ
MDN 1201	UniPlex II NRFit (E-Cath)	4048223-R20-0129CY

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
	Cannula/ needle: Facet/ Facet-S; Stimulation cable, injection tube, NanoLine, lateral orifice permanent cannula, NRFit	
MDN 1201	UniPlex® NanoLine® (For MultiSet) Cannula/ needle: SPROTTE®; Stimulation cable, injection tube, NanoLine®, permanent cannula, LUER	4048223-R20-0130CH
MDN 1201	UniPlex® II NRFit® (For E-Cath) Cannula/ needle: Facet/ Facet-S; Stimulation cable, injection tube, NanoLine®, permanent cannula, NRFit®	4048223-R20-0131CK
MDN 1201	Needle and kits - Plexus block / UniPlex® NanoLine® Cannula/ needle: Facet/ Facet-S; Stimulation cable, injection tube, NanoLine®, permanent cannula, LUER - R20-0132	4048223-R20-0132CM
MDN 1201	UniPlex® II NRFit® Cannula/ needle: SPROTTE®; Stimulation cable, injection tube, NanoLine®, permanent cannula, NRFit®	4048223-R20-0133CP
Puncture and positioning of cannula and catheter at the peripheral nerve and injection of anesthetic		
MDN 1201	Needle and kits - Plexus block/ PeriLong SPROTTE®	4048223-R20-0134CR
MDN 1201	Needle and kits - Plexus block/ PeriLong SPROTTE® NRFit®	4048223-R20-0135CT
MDN 1201	Needle and kits - Plexus block/ PeriLong NRFit®	4048223-R20-0136CV
Access to the target area and injection using ultrasound		
MDN 1201	Needle and kits - Plexus block/ SonoTAP® II	4048223-R20-0138CZ
MDN 1201	Needle and kits - Plexus block/ SonoTAP® II NRFit®	4048223-R20-0139D3
MDN 1201	Needle and kits - Plexus block/ SonoTAP® Cannula/ needle, Facet/ Facet-S, CornerStone, LUER	4048223-R20-0141CN
MDN 1201	Needle and kits - Plexus block/ SonoTAP® Cannula/ needle, Tuohy, CornerStone, LUER	4048223-R20-0143CS
Puncture, access to the target area, aspiration, injection, catheter placement. The catheters are intended to remain in the target area and constantly deliver a local anaesthetic from an external source.		
MDN 1201	SonoLong NanoLine® NRFit® Cannula/ needle, Facet/ Facet-S, NanoLine®, Cornerstone, Stimulation, NRFit®	4048223-R20-0147D2

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
MDN 1201	SonoLong NanoLine® NRFit® Cannula/ needle, Tuohy, NanoLine®, Cornerstone, Stimulation, NRFit®	4048223-R20-0148D4
MDN 1201	SonoLong NanoLine® Cannula/ needle, Facet/ Facet-S, NanoLine®, CornerStone, Stimulation, LUER	4048223-R20-0149D6
MDN 1201	Needle and kits - Plexus block/ SonoLong NanoLine® - R20-0151	4048223-R20-0151CR
MDN 1201	Needle and kits - Plexus block/ SonoLong NanoLine® - R20-0152	4048223-R20-0152CT
MDN 1201	SonoLong NanoLine® Cannula/ needle, SPROTTE® SPECIAL, NanoLine®, Cornerstone, Stimulation, NRFit®	4048223-R20-0153CV
MDN 1201	PlexoLong NanoLine® Cannula/ needle, Facet, Facet-S, NanoLine®, Stimulation, LUER	4048223-R20-0154CX
MDN 1201	Needle and kits - Plexus block/ PlexoLong NanoLine® - R20-0156	4048223-R20-0156D3
MDN 1201	PlexoLong NanoLine® Cannula/ needle, SPROTTE® SPECIAL, NanoLine®, Stimulation, LUER	4048223-R20-0157D5
MDN 1201	PlexoLong NanoLine® NRFit® Cannula/ needle, Facet, SPROTTE® SPECIAL, NanoLine®, Stimulation, NRFit®	4048223-R20-0158D7
MDN 1201	PlexoLong NanoLine® NRFit® Cannula/ needle, Facet, Facet-S, NanoLine®, Stimulation, NRFit®	4048223-R20-0160CS
MDN 1201	PlexoLong NanoLine® NRFit® Cannula/ needle, Tuohy, NanoLine®, Stimulation, NRFit®	4048223-R20-0161CU
Puncture and positioning of cannula and catheter at the peripheral nerves (where appropriate with the help of ultrasound and/ or nerve stimulation techniques) and injection of anesthetic		
MDN 1201	KombiPlex	4048223-R20-0164D2
MDN 1201	QInject	4048223-R20-0166D6
MDN 1201	SonoPlex II E-Cath	4048223-R20-0171CX
MDN 1201	SonoPlex® E-Cath®	4048223-R20-0172CZ
MDN 1201	SonoPlex® II E-Cath®	4048223-R20-0173D3

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Puncture and positioning of cannula and catheter at the peripheral nerve and injection of anesthetic		
MDN 1201	Needle and kits - Plexus block/ PeriLong - R20-0182	4048223-R20-0182D4
MDN 1201	PeriLong Cannula/ needle, Facet, Retaining Plate, Verweil cannula, LUER	4048223-R20-0183D6
Infiltration of local anesthetic in the surrounding tissue and near the joints.		
MDN 1201	InFiltr Cannula/needle: closed bevelled grind; 6 lateral openings on first 20mm	4048223-R20-0605DB
MDN 1201	Infiltration cannula Cannula/ Needle: Facet, glued tube, LuerLock, locking cap	4048223-R20-0606DD
The cannulas are intended to access the target area and administer a local anesthetic, which is output from an external source. Stimulation can be applied.		
MDN 1201	NerveStim Sono	4048223-R20-0900DG
Puncture, aspiration and injection in muscles, joints, tendons and ligaments		
MDN 1201	SonoMSK	4048223-R20-1092D9
Needles and systems breast nodes location (and other sites)		
Location and preoperative marking of mamma-results		
MDN 1201	Needles and systems breast nodes location (and other sites)/ Mammography localization set	4048223-R20-1070CX
MDN 1201	Needles and systems breast nodes location (and other sites)/ MammaLoc Sono	4048223-R20-1071CZ
Ophthalmology injection needles and kits – other		
Puncture of the retrobulbar space and peribulbar space, injection of anaesthetic		
MDN 1201	Ophthalmology injection needles and kits – other/ SonoEye	4048223-R20-0822DM
PERIDURAL / EPIDURAL SPINAL CATHETERS AND KITS – ACCESSORIES		
Fixation of catheter and filter		
MDN 1201	FixoLong with Filter	4048223-R20-0679E8
MDN 1201	FixoLong with Filter NRFit®	4048223-R20-0680DR
PERIPHERAL NERVOUS SYSTEM CATHETERS – OTHER		
The catheters are intended to remain in the target area and administer a local anaesthetic, which is output from an external source. Stimulation can be applied		
MDN 1201	NerveStim Flex	4048223-R20-0902DL

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Shearing biopsy needles		
Extraction of tissue specimens from soft tissue.		
MDN 1201	Hypodermic needles – others/ DeltaCut Coaxial sleeve oder Shearing biopsy needles/ DeltaCut Biops	4048223-R20-1011CF
Endotherapy devices - others		
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaPort Sleeve	4048223-R20-2059DJ
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaTec MAN TrocaTec AUTO	4048223-R20-2060D3
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaPort	4048223-R20-2061D5
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaReducer L TrocaReducer S	4048223-R20-2062D7
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaTube	4048223-R20-2063D9
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaTec Seal	4048223-R20-2068DK
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaPort System, modular: valve housing, reusable	4048223-R20-2071D8
MDN 1208	Endotherapy, trocars, single-use – accessories/ Valve insert top	4048223-R20-2083DF
Port for the introduction of trocar systems, endoscopes and endoscopic accessories into the surgical field.		
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaCone	4048223-R20-2094DL
MDN 1208	Endotherapy, trocars, single-use – accessories/ Hasson Cone	4048223-R20-2095DN
Performance of incisions in the body of the patient / tissue separation and reception of endoscopes and endoscopic accessories into the surgical field. Ensuring the tightness of trocar systems; regulation of the gas flow.		
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaStop	4048223-R20-2096DQ
Irrigation and aspiration of rinsing liquid in the operating area		
MDN 1208	FlowSys Seal	4048223-R20-2280DK

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
MDN 1208	Endotherapy, trocars, single-use – accessories/ FlowSys Tube SI-Systems: modular, metal/synthetic, 8 (2x4) lateral orifices, M8, reusable	4048223-R20-2258DS
MDN 1208	Endotherapy, trocars, single-use – accessories/ FlowSys Tube SI-Systems: modular, 4 lateral orifices, M8, reusable	4048223-R20-2259DU
MDN 1208	Endotherapy, trocars, single-use – accessories/ FlowSys Tube SI-Systems: modular, 4x4 (beehive) lateral orifices, M8, reusable	4048223-R20-2260DD
MDN 1208	Endotherapy, trocars, single-use – accessories/ FlowSys Tube SI-Systems: modular, distal needle (puncture/ injection/ aspiration), M8, reusable	4048223-R20-2261DF
Endotherapy, trocars, single-use - accessories		
MDN 1208	TrocaPort Seal	4048223-R20-2057DE
MDN 1208	TrocaTec Sealset	4048223-R20-2058DG
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaTec 2064	4048223-R20-2064DB
MDN 1208	Endotherapy, trocars, single-use – accessories/ EcoBalloon TrocaTec MAN EcoBalloon TrocaTec AUTO - 2065	4048223-R20-2065DD
MDN 1208	TrocaTec Sealset	4048223-R20-2066DF
MDN 1208	TrocaPort Sealset	4048223-R20-2067DH
MDN 1208	Endotherapy, trocars, single-use – accessories/ EcoBalloon TrocaPort -2070	4048223-R20-2070D6
MDN 1208	TrocaPort TOP	4048223-R20-2084DH
Reducing the diameter of the working channel. These reducing systems allow instruments with a diameter smaller than that of the trocar sleeve to be used without loss of pressure through the trocar sleeve.		
MDN 1208	Endotherapy, trocars, single-use – accessories/ Valve reducer 2080	4048223-R20-2080D9
MDN 1208	Endotherapy, trocars, single-use – accessories/ TrocaReducer	4048223-R20-2082DD
Handpieces, electrosurgical, reusable Irrigation and aspiration of rinsing liquid in the operating area		
MDN 1208	Handpieces, electrosurgical, reusable/ FlowSys FlowSys Duo	4048223-R20-2268DV

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
MDN 1208	Handpieces, electrosurgical, reusable/ FlowSys Eco FlowSys Access	4048223-R20-2269DX
MDN 1208	Handle SI-System, modular, lever valve/ valve, reusable	4048223-R20-2270DG
MDN 1208	Handpieces, electrosurgical, reusable/ FlowSys Ergo	4048223-R20-2271DJ
Pneumoperitoneal needles, Veress models Initial puncture, optionally followed by gas insufflation		
MDN 1208	Disposable Veress	4048223-R20-2180DE
MDN 1208	Pneumoperitoneal needles, Veress models/ Insufflation cannula acc. to Veress 2181	4048223-R20-2181DG
MDN 1208	Pneumoperitoneal needles, Veress models/ Cutting cannula for Veress 2182	4048223-R20-2182DJ
MDN 1208	Pneumoperitoneal needles, Veress models/ Insufflation cannula acc. to Veress 2183	4048223-R20-2183DL
MDN 1208	Pneumoperitoneal needles, Veress models/ Veress 2185 System: Introducer, Body, stainless steel, reusable	4048223-R20-2185DQ
MDN 1208	Pneumoperitoneal needles, Veress models/ Veress Modular System: Body, stainless steel, reusable 2186	4048223-R20-2186DS
Scalpel, single-use Incision of the carpal ligament with ultrasound-guided manual navigation, which allows real-time control of nerves, tendons and arteries throughout the procedure.		
MDN 1208	SonoCut, Scalpel, single-use Articl.1180-00-00	4048223-R20-0328D8
Neurological Stimulators Delivering of electrical current via compatible applied parts for stimulation of peripheral nerves		
MDA 0305	Neurological Stimulators	4048223-R20-0903DN
Neuromuscular stimulation equipment		
MDA 0305	Stim2Go	4048223-R20-0596E3

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Class IIb

MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Basis UDI-DI
Endoscopic electrosurgery electrodes, reusable/sterile			
Application of high-frequency alternating current for monopolar cutting and/or coagulation of soft tissue, ablation. Irrigation and aspiration of liquids or gases in the operating area.			
MDA 0312	L180602	FlowTube HF	4048223-R20-2110CR 4048223-R20-2111CT 4048223-R20-2112CV 4048223-R20-2113CX
MDA 0312	L180602	FlowTube HF-C	4048223-R20-2115D3 4048223-R20-2116D5 4048223-R20-2118D9
MDA 0312	L180602	FlowTube HF RET	4048223-R20-2120CU 4048223-R20-2121CW 4048223-R20-2123D2
MDA 0312	L180602	FlowTube HF-C RET	4048223-R20-2125D6 4048223-R20-2126D8
Instruments for mechanical cutting, monopolar cutting and coagulation during laparoscopic procedures			
MDA 0312	K0201010402	MonoTip II	4048223-R20-2147DG
MDA 0312	K0201010402	MonoTip METZENBAUM L MonoTip METZENBAUM M MonoTip METZENBAUM S MonoTip METZENBAUM P	4048223-R20-2150D5
Endoscopic electrosurgery electrodes, reusable			
Instruments for mechanical cutting, gripping, holding or clamping as well as for monopolar cutting and coagulation during laparoscopic procedures			
MDA 0312	L180602	MultiTip II	4048223-R20-2148DJ
MDA 0312	L180602	MultiTip METZENBAUM	4048223-R20-2155DF
MDA 0312	L180602	MultiTip	4048223-R20-2156DH
MDA 0312	L180602	ErgoForceps	4048223-R20-2170DB 4048223-R20-2174DK 4048223-R20-2176DP
MDA 0312	L180602	ErgoScissors	4048223-R20-2173DH
MDA 0312	L180602	ErgoClamp	4048223-R20-2175DM
MDA 0312	L180602	ErgoNeedle	4048223-R20-2177DR
MDA 0312	L180602	ErgoTop	4048223-R20-2225DB 4048223-R20-2226DD 4048223-R20-2228DH
MDA 0312	L180602	ErgoGrip	4048223-R20-2244DF
MDA 0312	L180602	ErgoFlex	4048223-R20-2245DH
MDA 0312	L180602	EcoFlex Mod EcoGrip Mod	4048223-R20-2246DK
MDA 0312	L180602	EcoFlex EcoGrip M	4048223-R20-2247DM

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MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Basis UDI-DI
		EcoGrip F	
MDA 0312	L180602	FlowSys ErgoHF	4048223-R20-2248DP
MDA 0312	L180602	TipRod Eco TipRod Ergo	4048223-R20-2250DA
MDA 0312	L180602	TipRod Ergo II	4048223-R20-2251DC
MDA 0312	L180602	TipTube	4048223-R20-2252DE
MDA 0312	L180602	TipTube II	4048223-R20-2253DG
MDA 0312	L180602	Guide Tube ErgoTube	4048223-R20-2255DL
Peripheral nervous system catheters and kits			
Access to and injections at peripheral nerves, where appropriate with the help of ultrasound and/ or nerve stimulation techniques; placement of catheters (Kit)			
MDN 1201	N010401	E-Cath II Tsui	4048223-R20-0342D2
MDN 1201	N010401	E-Cath II Tsui NRFit®	4048223-R20-0343D4
MDN 1201	N010401	E-Cath II Plus Tsui	4048223-R20-0344D6
MDN 1201	N010401	E-Cath II Plus Tsui NRFit®	4048223-R20-0345D8
MDN 1201	N010401	E-Cath® Plus Soft Tsui®	4048223-R20-0432D4
MDN 1201	N010401	E-Cath® NRFit® Tsui®	4048223-R20-0441D5
MDN 1201	N010401	E-Cath® Plus NRFit® Tsui®	4048223-R20-0442D7
MDN 1201	N010401	E-Cath® Tsui®	4048223-R20-0443D9
MDN 1201	N010401	E-Cath® Plus Tsui®	4048223-R20-0444DB
MDN 1201	N010401	E-Cath® Tsui®	4048223-R20-0536DH
MDN 1201	N010401	E-Cath® Plus Tsui®	4048223-R20-0537DK
Access to and injections at peripheral nerves, where appropriate with the help of ultrasound and/ or nerve stimulation techniques; placement of catheters-Stimulation can be applied (Kit)			
MDN 1201	N010401	E-Cath® Stim Plus	4048223-R20-0433D6
MDN 1201	N010401	E-Cath® Stim Tsui®	4048223-R20-0434D8
Access to the peripheral target area and injection, where appropriate with the help of ultrasound; placement of catheters (Kit)			
MDN 1201	N010401	Rectus Sheath NRFit®	4048223-R20-0416D6
MDN 1201	N010401	Fascia Iliaca Block	4048223-R20-0417D8
Puncture, access to the target area, aspiration, injection, catheter placement. The catheters are intended to remain in the target area and constantly deliver local anaesthetic emitted by an external source (Kit)			
MDN 1201	N010401	Rectus Sheath	4048223-R20-0418DA
The catheters are intended to remain in the target area (close to the peripheral nerves) and constantly deliver local anaesthetic emitted by an external source. Intended use of the E-Cath system: Access and injections to peripheral nerves, sometimes using ultrasound and/ or nerve stimulation techniques; catheter placement.			
MDN 1201	N010401	E-Cath Stim catheter	4048223-R20-0285DF
MDN 1201	N010401	Catheter Catheter, transparent, standard, accessories	4048223-R20-0269DH
MDN 1201	N010401	Catheter PlexoLong SONO	4048223-R20-0270D2

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MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Basis UDI-DI
		Catheter, transparent, helical coil, acces	
MDN 1201	N010401	StimuLong Cath	4048223-R20-0271D4
MDN 1201	N010401	StimuLong Sono Cath	4048223-R20-0272D6
MDN 1201	N010401	SonoLong Echo Cath	4048223-R20-0277DG
MDN 1201	N010401	SonoLong Sono Cath	4048223-R20-0278DJ
MDN 1201	N010401	PlexoLong NRFit® Cath	4048223-R20-0282D9
MDN 1201	N010401	SonoLong Echo NRFit® Cath	4048223-R20-0283DB
MDN 1201	N010401	SonoLong Sono	4048223-R20-0284DD
MDN 1201	N010401	E-Cath catheter NRFit®	4048223-R20-0286DH
MDN 1201	N010401	E-Cath catheter	4048223-R20-0287DK
MDN 1201	N010401	E-Cath catheter	4048223-R20-0289DP
MDN 1201	N010401	SonoLong Curl Echo catheter	4048223-R20-0291DA
MDN 1201	N010401	SonoLong Curl Echo/ Sono Catheter NRFit®	4048223-R20-0292DC
MDN 1201	N010401	E-Cath catheter	4048223-R20-0293DE
MDN 1201	N010401	E-Cath catheter	4048223-R20-0294DG
The catheters are intended to remain in the target area and constantly deliver a local anaesthetic from an external source.			
MDN 1201	N010401	InfiltraLong Forte Catheter	4048223-R20-0295DJ
MDN 1201	N010401	InfiltraLong Catheter NRFit®	4048223-R20-0299DS
MDN 1201	N010401	InfiltraLong Catheter	4048223-R20-0300CJ
MDN 1201	N010401	InfiltraLong Catheter	4048223-R20-0301CL
MDN 1201	N010401	InfiltraLong Catheter	4048223-R20-0306CW
MDN 1201	N010401	NerveStim E-Cath®	4048223-R20-0340CW
Dwell in the target area, continuous administration of anaesthetic/analgesic (Kit)			
MDN 1201	N010401	InfiltraLong NRFit®	4048223-R20-0446DF
MDN 1201	N010401	InfiltraLong (TUN) NRFit®	4048223-R20-0447DH
MDN 1201	N010401	InfiltraLong	4048223-R20-0450D6
MDN 1201	N010401	InfiltraLong	4048223-R20-0451D8
MDN 1201	N010401	InfiltraLong TUN	4048223-R20-0452DA
MDN 1201	N010401	InfiltraLong Duo	4048223-R20-0453DC
MDN 1201	N010401	InfiltraLong Sono	4048223-R20-0455DG
Puncture and positioning of cannula and catheter at the peripheral nerve and injection of anaesthetic (Kit)			
MDN 1201	N010401	KombiPlex B	4048223-R20-0438DG
MDN 1201	N010401	MultiSet NRFit®	4048223-R20-0439DJ
MDN 1201	N010401	MultiSet NanoLine®	4048223-R20-0440D3
Puncture and positioning of cannula and catheter at the peripheral nerve and injection of anaesthetic (Kit)			
MDN 1201	N010401	SonoLong SoftSecure	4048223-R20-0424D5
MDN 1201	N010401	SonoLong SoftSecure	4048223-R20-0427DB

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MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Basis UDI-DI
Puncture and positioning of cannula and catheter at the peripheral nerves (where appropriate with the help of ultrasound and/ or nerve stimulation techniques) and injection of anaesthetic (Kit)			
MDN 1201	N010401	StimuLong Sono Tsui®	4048223-R20-0425D7
MDN 1201	N010401	StimuLong Sono Tsui®	4048223-R20-0426D9
Puncture and positioning of cannula and catheter at the peripheral nerves (where appropriate with the help of ultrasound and/ or nerve stimulation techniques) and injection of anaesthetic Stimulation can be applied. (Kit).			
MDN 1201	N010401	StimuLong NanoLine®	4048223-R20-0410CS
MDN 1201	N010401	StimuLong NanoLine® acc. Kick	4048223-R20-0411CU
MDN 1201	N010401	StimuLong Sono acc. Kick	4048223-R20-0412CW
MDN 1201	N010401	StimuLong Sono NanoLine®	4048223-R20-0413CY
Puncture and positioning of cannula and catheter at the peripheral nerves and injection of anaesthetic Purpose of the individual components: (KiT) - Cannulae with various tip geometries: Puncture, access to the target area, aspiration. - Catheter: Remain in the target area and continuous administration of local anesthetic, which is output from an external source. - Syringe: Administration (injection) of liquid medicines. - Filter: Protection from the injection of micro-organisms or micro-particles. - Adapters: Proximal interface-connection to Luer-Lock, distal sealing, free flow and fixation for the catheter. - FixoLong Holder of the filter and fixation of the catheter in the vicinity of the point of egress - FixoCath Fixation of the catheter at the point of egress - Cable Connection or extension of the power lead to the catheter/to the cannula. - Tube Injecting of anesthetic/saline solution/D5W - Various accessories generally needed in hospitals: (swabs, tweezers, swab forceps etc.) Preparation or after-care of the operation location or puncture point)			
MDN 1201	N010401	InfiltraLong Duo Forte	4048223-R20-0464DH
Puncture, access to the target area, aspiration, injection, catheter placement. The catheters are intended to remain in the target area and constantly deliver a local anaesthetic from an external source. (Kit)			
MDN 1201	N010401	PlexoLong NanoLine® acc. Meier	4048223-R20-0403CV
MDN 1201	N010401	PlexoLong Sono NanoLine® acc. Meier	4048223-R20-0404CX
MDN 1201	N010401	PlexoLong NanoLine® NRFit® acc. Meier	4048223-R20-0405CZ
MDN 1201	N010401	PlexoLong Sono NanoLine® NRFit®	4048223-R20-0407D5
MDN 1201	N010401	StimuLong Sono II NanoLine®	4048223-R20-0414D2
MDN 1201	N010401	StimuLong Sono NRFit®	4048223-R20-0415D4
MDN 1201	N010401	SonoLong Sono NanoLine® SonoLong Sono PU	4048223-R20-0420CV

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MDA / MDN / IVR	EMDN / IVP	Name of device / device category	Basis UDI-DI
MDN 1201	N010401	SonoLong Echo NanoLine® SonoLong Echo Paed	4048223-R20-0421CX
MDN 1201	N010401	SonoLong Sono NanoLine® NRFit®	4048223-R20-0422CZ
MDN 1201	N010401	SonoLong Echo NanoLine® NRFit® SonoLong Echo Paed NRFit®	4048223-R20-0423D3
MDN 1201	N010401	SonoLong Curl Echo	4048223-R20-0430CY
MDN 1201	N010401	SonoLong Curl Echo NRFit®	4048223-R20-0431D2
MDN 1201	N010401	PlexoLong PlexoLong Cannula set	4048223-R20-0437DE
Puncture, access to the target area, aspiration, injection, catheter placement. The catheters are intended to remain in the target area and constantly deliver local anaesthetic emitted by an external source (Kit)			
MDN 1201	N010401	SonoTAP®	4048223-R20-0419DC
Orthopaedic cement preparation and application devices and kits			
MDN 1208	P09902	Cemento Needle Set for Cemento MP	4048223-R20-9009EL
MDN 1208	P09902	Cemento Pre-assembled customized procedure Kit: 1394-series, cannulas/ needles, accessories mento	4048223-R20-9013EB

For the initial placing on the market of class IIb implantable devices covered by this certificate, an EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.

Class III

MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Intended use: Lumbar puncture needles and kits		
MDN 1201	Quincke cannulas for lumbar puncture (LUER, NRFit®)	4048223-R20-1060CU 4048223-R20-1066D8
MDN 1201	SPROTTE® STANDARD (LUER/ NRFit®) Lumbar puncture	4048223-R20-1024CQ 4048223-R20-1025CS 4048223-R20-1026CU 4048223-R20-1027CW 4048223-R20-1048D6 4048223-R20-1050CR
Intended use: Needles and kits - peridural anaesthesia		
MDN 1201	CauDal (LUER/ NRFit®) Cannula/ Needle	4048223-R20-0070CQ 4048223-R20-0071CS 4048223-R20-0072CU
MDN 1201	Tuohy (LUER/ NRFit®) Cannula/ Needle	4048223-R20-0055CU 4048223-R20-0056CW 4048223-R20-0060CM 4048223-R20-0061CP 4048223-R20-0062CR 4048223-R20-0058D2 4048223-R20-0059D4

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MDA / MDN / IVR	Name of device / device category	Basis UDI-DI
Intended use: Needles and kits - spinal and peridural anaesthesia		
MDN 1201	SPROTTE® SPECIAL Cannula	4048223-R20-0035CN
MDN 1201	SPROTTE® STANDARD (LUER/ NRFit®) Anaesthesia	4048223-R20-0001C5 4048223-R20-0003C9 4048223-R20-0004CB 4048223-R20-0005CD 4048223-R20-0006CF 4048223-R20-0012CA 4048223-R20-0014CE 4048223-R20-0015CG 4048223-R20-0016CJ 4048223-R20-0024CH 4048223-R20-0025CK 4048223-R20-0027CP 4048223-R20-0033CJ 4048223-R20-0034CL 4048223-R20-0037CS
Intended use: Peridural/ epidural Catheters		
MDN 1201	EpiLong Cath / IntraLong Cath (LUER/ NRFit®) Catheters CNS (central nervous system)	4048223-R20-0220CK 4048223-R20-0225CV 4048223-R20-0228D3 4048223-R20-0245D3 4048223-R20-0246D5
Intended use: Biopsy needles and kits - others		
MDN 1201	Disposable Biopsy Needle	4048223-R20-1103CM
MDN 1201	Disposable Biopsy Needle Sedan	4048223-R20-1102CK
Intended use: Needles and kits - spinal anaesthesia		
MDN 1201	Quincke (Luer / NRFit®) Anaesthesia	4048223-R20-0047CV 4048223-R20-0048CX 4048223-R20-0053CQ

For the initial placing on the market of class III devices covered by this certificate, an EC EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification GmbH Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Certificate valid from	Certification Notice Reference	Action
00, Rev. 00	2021-01-27	--	first issue
00, Rev. 01	2021-08-12	--	revised
00, Rev. 02	2021-09-17	--	revised
01, Rev. 00	2022-07-08	CNo51268-00, Rev. 0	revised
01, Rev. 01	2022-11-11	CNo51268-00, Rev. 1	revised
01, Rev. 02	2023-07-24	CNo51268-00, Rev. 2	revised
02, Rev. 00	2023-12-22	CNo51268-00, Rev. 3, 4	revised
02, Rev. 01	2024-09-09	CNo51268-00, Rev. 5	revised
02, Rev. 02	2024-12-23	CNo51268-00, Rev. 6	revised
03, Rev. 00	2025-02-17	CNo51268-01, Rev. 0	reissued
03, Rev. 01	2025-02-18	CNo51268-01, Rev. 1	revised
04	2025-04-30	CNo51268-01, Rev. 2	revised