

To be forwarded to: **TO WHOM IT MAY CONCERN**

Declaration on application of (EU) 2023/607 of March 15th 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Published in the Official Journal of the European Union on March 20th 2023

Hereby I in my capacity as Director Regulatory Affairs, Person Responsible for Regulatory Compliance and Safety Officer for Medical Devices at PAJUNK® GmbH Medizintechnologie I confirm:

The devices listed below and covered by the scope of the Certificates 51268-16-02 (Annex II, 3) and 51268-17-02 (Annex V, 3) issued under 93/42/EEC are subject to the scope of (EU) 2023/607 amending (EU) 2017/745, especially the modification of Article 120.

(EU) 2023/607 is fully applicable to these devices and the extended period of validity for these certificates is hereby confirmed by PAJUNK GmbH Medizintechnologie and confirmed by the Notified Body DEKRA.

Class II a (non-active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101	37148 Laparoscopic sleeve MIS (Minimal Invasive Surgery) Systems:	EcoFlex Mod FlowSys Tube 1298-Series 1295-Series 1288-Series 1000-Series
Ila	MD0101	45342 Laparoscopic trocar sleeve anchor Modular Trocar System	TrocaStop TrocaCone Hasson Cone Fixation, abdominal wall

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101	37148 Laparoscopic sleeve Modular reusable systems	TrocaTec TrocaPort Reusable guide tube for trocar sleeve Reusable Modular Trocar Sleeve 1287-series
Ila	MD0101	45645 Laparoscopic sleeve seal Modular reusable systems	TrocaPort 1287-series
Ila	MD0101 MDS7006	45597 Trocar sleeve seal/port reducer Modular reusable systems: Disposable Valve Top	TrocaPort SEAL TrocaTec SEAL TrocaPort SEALSET TrocaTec SEALSET TrocaCap TrocaPort TOP TrocaReducer TrocaReducer L TrocaReducer S EcoBalloon TrocaPort MultiPort CAP 1287-series 1285-series
Ila	MD0101	45597 Trocar sleeve seal/ port reducer Modular reusable systems: Reusable valve top	TrocaTec Reducer sleeve Modular reusable trocar housing
Ila	MD0102 MDS7006	12750 Spring-loaded pneumoperitoneum needle, single-use Veress-Needle-Systems, fully disposable and disposable sharp outer needle for reusable modular system	Insufflation cannulae acc. Veress
Ila	MD0102	46329 Spring-loaded pneumoperitoneum needle, reusable Veress-Needle-Systems, fully reusable System and reusable insufflation body for reusable modular system	Insufflation cannulae acc. Veress
Ila	MD0102 MDS7006	33069 Brachytherapy needle Needle for Seed placement and implantation	DeltaSeed DeltaFix
Ila	MD0102 MDS7006	46328 Simple pneumoperitoneum needle Veress-Needle-Systems, semi-Reusable	Insufflation cannulae acc. Veress

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0102 MDS7006	46329 Spring-loaded pneumoperitoneum needle, reusable Veress-Needle-Systems, Semi-reusable, initially sterilized	Insufflation cannulae acc. Veress
Ila	MD0102 MDS7006	16858 Catheter injection port	Injection tube, Y-tube Injection tube, Y-tube NRFit®
Ila	MD0102 MDS7006	35375 Stopcock	Stopcock/ 3-way-valve Stopcock/ 3-way-valve NRFit®
Ila	MD0106	47829 Surgical instrument handle Handles for Suction-Irrigation Systems	FlowSys Eco FlowSys Twin FlowSys FlowSys ACCESS Valve Handle Pistol Handle FlowSys Ergo

Class II a (active):

Class	MD-Code	GMDN	Brand
Ila	MD1104 MDS7006	58990 Side-notch biopsy gun, single-use Automated Disposable Biopsy System with/ without trocar	CoreCut PrimoCut
Ila	MD1104	22724 Side-notch biopsy gun, reusable Biopsy System: Reusable gun and disposable needles with/ without trocar	DeltaCut

Class II b (non-active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
Iib	MD0101 MDS7006	46383 Peripheral anaesthesia catheter set, non-medicated Peripheral catheters for continuous anaesthesia and analgesia	PlexoLong Cath PlexoLong Cath NRFit® StimuLong Cath StimuLong Cath NRFit® Plexus Cath Plexus Cath NRFit® SonoLong Curl Echo Cath SonoLong Curl Echo Cath NRFit® InfiltraLong Catheter Peripheral standard catheter Peripheral standard catheter NRFit® Peripheral coiled catheter Peripheral coiled catheter NRFit® Peripheral stimulation catheter Peripheral stimulation catheter NRFit® Peripheral coiled stimulation catheter Peripheral coiled stimulation catheter NRFit® Catheter Seldinger technique Catheter Seldinger technique NRFit®

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD0102 MDS7006	47737 Orthopaedic cement injection cannula Disposable needles for cement injection	Special-Vertebroplasty Cannula acc. To Gangi, Needles/ cannulas/ Trocars for Cemento disposable gun Needles/ cannulas/ Trocars for Cemento reusable gun 1394-Series 1384-Series 1392-Series 1393-Series 1382-Series
IIb	MD0106 MDS7006	46542 Elastomeric infusion pump system	FuserPump FuserPump NRFit®

Class II b (active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD 0102 MDS7006	58739 - Radio-frequency ablation system probe cannula, single-use Thermolesion needles, cannulas and trocars for RF-Ablation	RFTL Needle RFTL Needle NRFit® RFTL SONO RFTL Sono NRFit® PulsedRF PulsedRF Sono Thermolesion cannula/ needle Thermolesion cannula/ needle NRFit® RGN cannula/ needle RGN Cannula/ Needle NRFit®
IIb	MD1104	33596 Endoscopic electrosurgical coagulator/cutter, unipolar, reusable Modular HF/SI-System: Rod, Handle, tube, figure	FlowTube HF FlowTube HF-C FlowTube HF RET FlowTube HF-C RET Handle HF Handle HF-C J-Hook Right Angle (90°) 45° angle Needle Spatula Ballpoint Conical 1299-Series 2000-series (standalone, integrated handle)
IIb	MD1104	35732 Rigid endotherapy biopsy forceps, reusable Modular HF/SI-System: Rod, Handle, tube, figure	ErgoForceps ErgoTop biopsy punch, serration biopsy punch biopsy punch, spoon shaped Biopsy spoon forceps with fixation thorn Biopsy punch, spoon shaped, fixation thorn Biopsy Kit 1292-Series

Class	MD-Code	GMDN	Brand/ variants/ item code group
I Ib	MD1104	35080 Laparoscopic grasping forceps Modular HF/SI-System: Rod, Handle, tube, figure	ErgoForceps ErgoClamp ErgoTop BABCOCK COLLIN MONTGOMERY KOCHER DE BAKEY MultiTip MARYLAND Universal Claw type DOLPHIN Reservoir Atraumatic OVIDUCT MOUSE TOOTH ALLIGATOR MIXTER ALLIS MAXI GRIP DORSEY MultiTip ENDOCLINCH KELLY AGGRESSIVE RETRACTION DUCKBILL Grasper Kit Scissor Kit Scissor kit MonoTip Clamping Kit 1292-Series 1293-Series
I Ib	MD1104	35080 Laparoscopic grasping forceps Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip MARYLAND MonoTip ENDOCLINCH
I Ib	MD1104	37148 Laparoscopic sleeve HF and SI Systems:	FlowTube HF FlowTube HF-C 1299-Series

Class	MD-Code	GMDN	Brand/ variants/ item code group
I Ib	MD1104	38727 General-purpose surgical scissors, reusable Modular HF/SI-System: Rod, Handle, tube, figure	MultiTip METZENBAUM (M, L, S, P) ErgoScissors ErgoTop Dissection SCISSORS curved/ straight Dissection SCISSORS METZENBAUM Hook Type SCISSORS Hooked Scissors METZENBAUM Micro Scissors curved/ straight Peritoneal Scissors curved/ straight Fine Serration Curved Surgical scissors Wondercut Metzenbaum Soft Surgical Spoon Scissor Kit 1292-Series 1293-Series
I Ib	MD1104	38727 General-purpose surgical scissors, reusable Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip METZENBAUM M
I Ib	MD1104 MDS7006	58949 General-purpose surgical scissors, single-use Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip METZENBAUM L MonoTip METZENBAUM M MonoTip METZENBAUM S MonoTip METZENBAUM P Scissor Kit
I Ib	MD1104	36136 Haemostatic knife Modular HF/SI-System: Rod, Handle, tube, figure	FlowTube HF FlowTube HF-C FlowTube HF RET FlowTube HF-C RET Handle HF Handle HF-C 1299-Series 2000-series (standalone, integrated handle)
I Ib	MD1104 MDS7006	36136 Haemostatic knife Modular HF/SI-System: Rod, Handle, tube, figure	1299-Series FlowTube HF RET
I Ib	MD1104	12726 Needle holder, reusable Modular HF/SI-System: Rod, Handle, tube, figure	ErgoNeedle ErgoSys Needle Holder Kit 1292-Series 1000er series

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD1104	47829 Surgical instrument handle Handles for Suction-Irrigation/ HF-Systems	EcoGrip Mod ErgoFlex ErgoGrip EcoFlex EcoGrip EcoGrip-M EcoGrip-F FlowSys Eco HF FlowSys Ergo HF FlowSys Twin HF FlowSys HF TipRatchet TipHandle Pistol Handle Lever Valve Valve Handle Trumpet Valve Handle Double Trumpet Valve Handle1292-Series 1293-series 1299-series 1000er-series EcoHF-Sys
IIb	MD1104	11798 Utility forceps, reusable Modular inserts with integrated rod	Endo hook, fan shaped
IIb	MD1104	38661 Rigid endoscopic grasping forceps, reusable MIS-HF-System	ErgoSys Scissor Kit
IIb	MD1104	33596 Endoscopic electrosurgical coagulator/cutter, unipolar, reusable MIS-HF-System: Connection Rods, guide tubes	TipRod Eco TipRod Ergo TipTube ErgoTube

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

Class	MD-Code	GMDN	Brand/ variants/ item code group
Is	MD0101 MDS7006	34864 Adhesive bandage Extracorporal Catheter and filter fixation devices	FixoLong FixoCath

Class	MD-Code	GMDN	Brand/ variants/ item code group
Is	MD0101 MDS7006	43668 Cerebrospinal fluid manometer, mechanical Manometer for measuring liquor pressure	Spinal Manometer with 3-way-valve Spinal Manometer with 3-way-valve SURETY® Spinal Manometer with 3-way-valve NRFit® Spinal Manometer Extension Spinal Manometer Extension SURETY®
Is	MD0101 MDS7006	61722 Nerve-block injection manometer Pressure Control unit	NerveGuard
Is	MD0102 MDS7006	45018 Non-implantable needle guide, single-use Needles/ trocars for needle-through-needle/ catheter-through-needle and initial puncture	GCS Guidance Instrument GLOA
Is	MD0102 MDS7006	44884 Low-resistance syringe	LOR-Syringe LOR-Syringe SURETY® LOR-Syringe NRFit® VPC
Is	MD0102 MDS7006	47191 Anaesthesia conduction catheterization kit	Insertion aid – individual –
Is	MD0102 MDS7006	33961 Surgical procedure kit, general-purpose, single-use, non-medicated	Customized Procedure Kit: Common Hospital Supply
Is	MD0102 MDS7006	16858 Catheter injection port	Hose/ Valve Injection valve, Y-tubing, sealing cap, LUER Locking Cap Locking Cap NRFit®
Is	MD0102 MDS7006	16858 Catheter injection port	Hose/ tube Subassembly: Injection tube
Is	MD0102 MDS7006	16858 Catheter injection port	Perfusion/ Infusion Line NRFit®
Is	MD0102 MDS7006	31245 Anaesthesia conduction filter	Particle filter
Is	MD0106 MDS7006	46542 Elastomeric infusion pump system	FuserPump Filler FuserPump Filler NRFit® SPIKE SPIKE NRFit® Connector
Is	MD1103 MDS7006	47487 Electrical-only medical device connection cable, reusable Cable for MultiStim nerve stimulator series, sterile, reusable	Extension cable

Class	MD-Code	GMDN	Brand/ variants/ item code group
Is	MD1104 MDS7006	47143 Electrical-only medical device connection cable, single-use Extension cable, disposable	Extension cable
Is	MD0101 MDS7006	46308 - Epidural/ intrathecal anaesthesia kit Fixation System for EpiSpin, sterile, accessory	Locking System EpiSpin Lock
Is	MD0101 MDS7006	35212 Spinal needle, single-use Retaining plate/ Wings for needle, sterile, accessory	Retaining plate/ Wings
Is	MD0102 MDS7006	16266 Medication transfer needle, filtering	Drawing up filter needle Drawing up Needle Drawing up filter straw

Procedure packs according to article 12 of directive 93/42/EEC:

Class	MD-Code	GMDN	Brand/ variants/ item code group
Is	MD0101 MDS7006	33961 General/plastic surgical procedure kit, non-medicated, single-use Customized Procedure Kit for common hospital use	Basisset Grundset Basics set Customized Convenience Kit general

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101 MDS7006	46382 Peripheral anaesthesia single-administration set, non-medicated Customized Procedure Kit for peripheral Nerve Block with/ without stimulation	Grundset Customized Convenience Kit peripheral
Ila	MD0101 MDS7006	47797 Pleural/ peritoneal drainage catheterization kit Customized Procedure Kit for drainage and/or aspiration	Grundset Customized Convenience Kit drainage and/or aspiration

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101 MDS7006	33961 General/plastic surgical procedure kit, non-medicated, single-use Customized Procedure Kit for general/plastic surgical	Basisset Grundset Basics set Customized Convenience Kit general
Ila	MD0101 MDS7006	16833 Bone marrow biopsy procedure kit Customized Procedure Kit for bone marrow biopsy	Grundset Customized Convenience Kit marrow biopsy

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ilb	MD0102 MDS7006	16472 Cement dispenser, orthopaedic Systems/ Kits for cement injection (Cementoplasty, cyphoplasty, vertebroplastie)	Kit for Cemento reusable Gun Kit for/ with Cemento disposable gun
Ilb	MD0101 MDS7006	33961 General/plastic surgical procedure kit, non-medicated, single-use Customized Procedure Kit for general/plastic surgical	Basisset Grundset Basics set Customized Convenience Kit general
Ilb	MD0101 MDS7006	46383 Peripheral anaesthesia catheter set, non-medicated Pre-Assembled Procedure Kit for peripheral Nerve Block with/ without stimulation	PlexoLong - Series SonoLong- Series StimuLong - Series MultiSet - Series KombiPlex - Series E-Cath – Series PeriLong - Series
Ilb	MD0101 MDS7006	46383 Peripheral anaesthesia catheter set, non-medicated Customized Procedure Kit for peripheral Nerve Block with/ without stimulation	Basisset Grundset Basics set Customized Convenience Kit Peripheral
Ilb	MD0101 MDS7006	46383 Peripheral anaesthesia catheter set, non-medicated Pre-assembled kits for wound infiltration/ infiltration analgesia	InfiltraLong - Series Fuser Pump - Series Fascia Iliaca Block – Series Rectus Sheath – Series SonoTap - Series
		46383 Peripheral anaesthesia catheter set, non-medicated Customized Procedure Kit for wound infiltration/ infiltration analgesia	Grundset Customized Convenience Kit Peripheral

III	Kits for regional anaesthesia contacting the central nervous system		
MD0101 MDS7006	34845 - Intrathecal anaesthesia kit Customized Procedure Kit for lumbar puncture	Grundset Customized Convenience Kit Spinal	
MD0101 MDS7006	34842 - Epidural anaesthesia kit, non-medicated Pre-Assembled Procedure Kit for continuous epidural Anaesthesia	EpiLong - Series StimuLong - Series Tuohy - Series Fast Track - Series	
	34842 - Epidural anaesthesia kit, non-medicated Customized Procedure Kit for continuous epidural Anaesthesia	Grundset Customized Convenience Kit Epidural	
	46308 - Epidural/ intrathecal anaesthesia kit Pre-Assembled Procedure Kit for combined spinal- epidural Anaesthesia	EpiSpin - Series	
	46308 - Epidural/ intrathecal anaesthesia kit Customized Procedure Kit for combined spinal- epidural Anaesthesia	Grundset Customized Convenience Kit Spinal - Epidural	
	34845 - Intrathecal anaesthesia kit Pre-Assembled Procedure Kit for spinal Anaesthesia	IntraLong - Series SPROTTE® - Series CauDal - Series	
	34845 - Intrathecal anaesthesia kit Customized Procedure Kit for spinal Anaesthesia	Grundset Customized Convenience Kit Spinal	

As executed:

Geisingen, 2023-03-21

Ort, Datum *Issued*



Digital unterschrieben
von

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Datum: 2023.03.21

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Christian G. H. Quass

Director Regulatory Affairs & Safety Officer for Medical Devices

PAJUNK® GmbH Medizintechnologie

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KONFORMITÄTSERKLÄRUNG

*DECLARATION DE CONFORMITÉ/ DECLARATION OF CONFORMITY/
DICHIARAZIONE DI CONFORMITÀ*

Wir / Nous / We / Noi,	PAJUNK® GmbH Medizintechnologie Karl-Hall-Str. 1, 78187 Geisingen, Baden-Württemberg, Germany		
erklären in alleiniger Verantwortung, dass das Medizinprodukt/ déclarons sous notre propre responsabilité que le dispositif médical de / declare on our own responsibility that the medical device / dichiariamo sotto propria responsabilità che il dispositivo medico:			
Typ/ Type Details see annex	PrimoCut		
MDD Annex IX	Class 2a, Rule 11 Active		
UMDN	17-848 Biopsiepistole		
GMDN	58990 Side-notch biopsy gun, single-use		
PAJUNK®-No.	R15-1013		
DIMDI §25 MPG (Germany only)	DE/CA39/12/Ä230Ä1		
allen Anforderungen der Medizinprodukte Richtlinie 93/42/EWG entspricht./ remplit toutes les exigences de la 93/42/CEE./ meets all the provisions of the Medical Devices Directive 93/42/EEC./ adempie a tutte le esigenze della Direttiva 93/42/CEE.			
Zertifikat/ certificat/ certificado/ certificato/ certificate	EN ISO 13485:2016	<input checked="" type="checkbox"/> 51268-14-01	2021-03-22 – 2024-03-21
	93/42/EEC Annex II, 3	<input checked="" type="checkbox"/> 51268-16-02	2018-03-22 – 2023-03-21
	93/42/EEC Annex V	<input type="checkbox"/> 51268-17-02	2018-03-22 – 2023-03-21

Benannte Stelle:

Organisme notifié/ Notified body/ Organo notificato

DEKRA Certification GmbH, Notified Body code: 0124

Handwerkstraße 15, 70565 Stuttgart

Konformitätsbewertungsverfahren:

Procédure d'évaluation de la conformité/

Conformity assessment procedure:/

Procedimento d'evaluazione della conformità:

MDD Annex II

MDD Annex II excluding II. 4

MDD Annex V.3

MDD Annex VII (ohne/ without NB 0124)

Gültig / valide / válida/ valid/ valida:

2018-03-22 – 2023-02-21

Geisingen, 2021-04-06

Ort, Datum / lieu, date/ place, date / luogo, data

Christian G. H. Quaß, Director Regulatory Affairs, Safety Officer, PRRC
Person Responsible for Regulatory Compliance (EU) 2017/745, Article 15-3b-e

Name und Funktion / nom et fonction/ name and function / nome e funzione

Annex R15-1013.docx

Die Konformitätserklärung R15-1013.docx schließt die folgenden Artikelnummern ein:

La declaración de conformidad R15-1013.docx incluida los artículos siguientes.

La dichiarazione di conformità R15-1013.docx inclusa seguenti articoli.

La declaration de conformité R15-1013.docx ferme des articles suivantes.

Items covered by the declaration of conformity R15-1013.docx

415S120100	PrimoCut Semi-Automated Disposable Biopsy System 1,20mm (18G) x 100mm
415S120150	PrimoCut Semi-Automated Disposable Biopsy System 1,20mm (18G) x 150mm
415S120200	PrimoCut Semi-Automated Disposable Biopsy System 1,20mm (18G) x 200mm
415S120250	PrimoCut Semi-Automated Disposable Biopsy System 1,20mm (18G) x 250mm
415S120280	PrimoCut Semi-Automated Disposable Biopsy System 1,20mm (18G) x 280mm
415S160100	PrimoCut Semi-Automated Disposable Biopsy System 1,60mm (16G) x 100mm
415S160150	PrimoCut Semi-Automated Disposable Biopsy System 1,60mm (16G) x 150mm
415S160200	PrimoCut Semi-Automated Disposable Biopsy System 1,60mm (16G) x 200mm

Geisingen, 2021-04-06

place, date

Christian G. H. Quaß, Director Regulatory Affairs, Safety Officer, PRRC
Person Responsible for Regulatory Compliance (EU) 2017/745, Article 15-3b-e
Name und Funktion / nom et fonction/ name and function / nome e funzione

ANNEX-PN1184

R15-1013.docx

1 / 1

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
PAJUNK GmbH Medizintechnologie

Karl-Hall-Straße 1, 78187 Geisingen, Germany

Certified location:

Karl-Hall-Straße 1, 78187 Geisingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51268-Z3-00, the decision dated 2018-03-20 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-03-22 to 2023-03-21

Registration No.: 51268-16-02



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-03-20
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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

ZLG-BS-295.10.02

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class II a (non-active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101	37148 Laparoscopic sleeve MIS (Minimal Invasive Surgery) Systems:	EcoFlex Mod FlowSys Tube 1298-Series 1295-Series 1288-Series 1000-Series
Ila	MD0101 MDS7006	45342 Laparoscopic trocar sleeve anchor Balloon Systems for fixation; 1285-series modular disposable and 1283-/ 1284-Series fully disposable	EcoBalloon RA(-S) EcoBalloon URO(-S) EcoBalloon SB EcoBalloon SL(-S) MonoBalloon RA(-S) MonoBalloon URO(-S) MonoBalloon SB MonoBalloon SL(-S) VarioBalloon RA(-S) VarioBalloon URO(-S) VarioBalloon SB VarioBalloon SL(-S) VarioBalloon Duo (DIL(-BI/XL) + RA/URO/SB/SL) MonoBalloon Duo (DIL(-BI/XL) + RA/URO/SB/SL) EcoBalloon Duo (DIL(-BI/XL) + RA/URO/SB/SL)
Ila	MD0101	45342 Laparoscopic trocar sleeve anchor Modular Trocar System	TrocaStop TrocaCone Hasson Cone Fixation, abdominal wall
Ila	MD0101	37148 Laparoscopic sleeve Modular reusable systems	TrocaTec TrocaPort Reusable guide tube for trocar sleeve Reusable Modular Trocar Sleeve 1287-series
Ila	MD0101	45645 Laparoscopic sleeve seal Modular reusable systems	TrocaPort 1287-series
Ila	MD0101 MDS7006	45597 Trocar sleeve seal/port reducer Modular reusable systems: Disposable Valve Top	TrocaPort SEAL TrocaTec SEAL TrocaPort SEALSET TrocaTec SEALSET TrocaCap TrocaPort TOP TrocaReducer TrocaReducer L TrocaReducer S EcoBalloon TrocaPort MultiPort CAP 1287-series 1285-series
Ila	MD0101	45597 Trocar sleeve seal/ port reducer Modular reusable systems: Reusable valve top	TrocaTec Reducer sleeve Modular reusable trocar housing
Ila	MD0101 MDS7006	37148 Laparoscopic sleeve Modular disposable systems	TrocaSys 1289-series: TrocaSys SLEEVE

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101 MDS7006	42412 Laparoscopic trocar/sleeve Modular disposable systems	TrocaSys: TrocaSys SHIELD TrocaSys PYRAMID TrocaSys BLUNT TrocaSys PROTECT TrocaSys HASSON TrocaSys VIEW TrocaSys Double Kit TrocaSys Triple Kit TrocaSys Duo PROTECTTrocaSys Duo SHIELD TrocaSys Duo PYRAMID TrocaSys Duo BLUNT 1289-series
Ila	MD0101 MDS7006	42412 Laparoscopic trocar/sleeve	1282-Series MultiPort PROTECT MultiPort VIEW MultiPort CAP
Ila	MD0101 MDS7006	16833 Bone marrow biopsy procedure kit Cannula-trocar-system for biopsy of bone and bone Marrow	TrokaBone TrokaBone Sternal TrokaCut
Ila	MD0101 MDS7006	35886 Body aspiration needle, single-use Aspiration and injection needles of common hospital supply Cannulas for invasive prenatal diagnosis	Tapered Needles - Chiba - Chiba Sono - Chiba NRFit® - Chiba Sono NRFit® Dual cannula System Dual Cannula System NRFit® Triple Cannula System Triple Cannula System NRFit® PTC PTC NRFit®
Ila	MD0101 MDS7006	47540 Soft-tissue biopsy needle, single-use Needles for core biopsy and aspiration	DeltaCut needle
Ila	MD0101 MDS7006	16835 Soft-tissue biopsy procedure kit, non-medicated	Dr. Steinhoff Kit
Ila	MD0101 MDS7006	61546 Nerve-locating anaesthesia needle Needles for peripheral nerve block	UniPlex UniPlex NanoLine KombiPlex B UniPlex NanoLine SURETY® SonoPlex STIM SonoPlex STIM SURETY® UniPlex II UniPlex II NRFit® SonoPlex II SonoPlex II NRFit®

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101 MDS7006	61547 Nerve-block sharp needle Needles for peripheral nerve block	SonoTAP SonoTAP NRFit® SonoTAP II SonoTAP II NRFit® SonoBlock SonoBlock NRFit® SonoBlock II SonoBlock II NRFit® MultiInject MultiInject NRFit® MultiInject Sono MultiInject Sono NRFit® SonoMSK SonoMSK NRFit® UniMSK
Ila	MD0101 MDS7006	61547 Nerve-block sharp needle Needles for injection and aspiration procedures	QInject
Ila	MD0101 MDS7006	61547 Nerve-block sharp needle Needles for infiltration/ injection	InFiltr
Ila	MD0101 MDS7006	61546 Nerve-locating anaesthesia needle Needles for peripheral nerve block and catheter placement	SonoLong NanoLine SonoLong NanoLine Tuohy SonoLong NanoLine NRFit® SonoLong NanoLine Tuohy NRFit® PlexoLong NanoLine PlexoLong NanoLine NRFit®
Ila	MD0101 MDS7006	45018 Non-implantable needle guide, single-use Needles/ trocars for needle-through-needle/ catheter-through-needle and initial puncture	IntroDucer IntroDucer NRFit® Initial Puncture needle/ Pravaz Introducer 2.G Introducer 2.G NRFit® Introducer Sono Introducer Sono NRFit® GCS Guidance Instrument GLOA TIPPS-Placement needle
Ila	MD0101 MDS7006	45018 Non-implantable needle guide, single-use Trocars for biopsy system	DeltaCut Trocar/ Coaxial Sleeve PrimoCut Trocar/ Coaxial Sleeve CoreCut Trocar/ Coaxial Sleeve
Ila	MD0101 MDS7006	58865 Vascular catheter introduction kit, non-steerable Needle/ kit for placement of central venous catheter	Vascular Sono Vascular Sono NRFit® Tsui E-IV
Ila	MD0101 MDS7006	45018 Non-implantable needle guide, single-use Needles/ trocars for tunnelisation (e. g. of a catheter)	Split cannula/ Tearaway needle Indwelling Catheter/ Permanent Cannula
Ila	MD0101 MDS7006	46801 Subcutaneous catheter tunneler, single-use Needles/ trocars for tunnelisation (e.g. of a catheter)	Tunneler/ Awl
Ila	MD0101 MDS7006	46115 General-purpose catheter connector Adapter for catheter/ tube connection	Clamping Adapter (different colours) Clamping Adapter SURETY® Clamping Adapter NRFit®

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0101 MDS7006	31245 Anaesthesia conduction filter Filter for injecting agents	Bacterial Filter 0,2 µm (LUER; SURETY®; NRFit®) Filter 0,5 µm LUER; NRFit®)
Ila	MD0102 MDS7006	12750 Spring-loaded pneumoperitoneum needle, single-use Veress-Needle-Systems, fully disposable and disposable sharp outer needle for reusable modular system	Insufflation cannulae acc. Veress
Ila	MD0102	46329 Spring-loaded pneumoperitoneum needle, reusable Veress-Needle-Systems, fully reusable System and reusable insufflation body for reusable modular system	Insufflation cannulae acc. Veress
Ila	MD0102 MDS7006	46669 Breast ductography cannula	Galactography kit
Ila	MD0102 MDS7006	33069 Brachytherapy needle Needle for Seed placement and implantation	DeltaSeed DeltaFix
Ila	MD0102 MDS7006	47714 Subdermal needle Electrode Needles for injection of Botulinumtoxin	Bo-Inject-Series: Bo-NanoInject Bo-Inject-Series: Bo-NanoInject NRFit® Bo-Inject-Series: Bo-SonoInject Bo-Inject-Series: Bo-SonoInject NRFit® Bo-Inject-Series: Stimulation-Cable for needle, Accessory
Ila	MD0102 MDS7006	45130 Tissue extraction bag	Resection Bag
Ila	MD0102 MDS7006	58742 Wound drainage bag	MultiPort Bag
Ila	MD0102 MDS7006	35824 Closed-wound drainage kit, general-purpose	Quadrain F10 Quadrain F12 Quadrain F15
Ila	MD0102 MDS7006	46328 Simple pneumoperitoneum needle Veress-Needle-Systems, semi-Reusable	Insufflation cannulae acc. Veress
Ila	MD0102 MDS7006	46329 Spring-loaded pneumoperitoneum needle, reusable Veress-Needle-Systems, Semi-reusable, initially sterilized	Insufflation cannulae acc. Veress
Ila	MD0102 MDS7006	47017 General-purpose syringe, single-use Injection syringes, different volumes	Injection Syringes Injection Syringes NRFit® LOCK Injection Syringes NRFit® slip
Ila	MD0102 MDS7006	61513 Endoscopic gel implant needle	Tapered cannula – VUR Tapered cannula – VUR NRFit®
Ila	MD0102 MDS7006	16858 Catheter injection port	Injection tube, Y-tube Injection tube, Y-tube NRFit®
Ila	MD0102 MDS7006	35375 Stopcock	Stopcock/ 3-way-valve Stopcock/ 3-way-valve NRFit®

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
Ila	MD0105 MDS7006	46910 Ophthalmic cannula, infusion Augenkanüle nach Atkinson	SonoEye SonoEye NRFit®
Ila	MD0106	60417 Surgical instrument cleaning adaptor	Cleaning Adapter LUER, LUER LOCK
Ila	MD0106	47829 Surgical instrument handle Handles for Suction-Irrigation Systems	FlowSys Eco FlowSys Twin FlowSys FlowSys ACCESS Valve Handle Pistol Handle FlowSys Ergo
Ila	MD0106	12291 Rigid optical Laparoscope Optical Endoscopes/ Laparoscopes	502-series
Ila	MD0106 MDS7006	44794 Surgical balloon dissector Balloon Systems for distension, 1285-series modular disposable and 1284-Series fully disposable	Eco Balloon DIL EcoBalloon DIL-XL EcoBalloon DIL-BI MonoBalloon DIL MonoBalloon DIL-XL MonoBalloon DIL-BI
Ila	MD0102 MDS7006	40808 Implantable lesion localization marker Mammography Localisation-Puncturing-kit	MammaLoc SONO MammaLocalization Kit
Ila	MD0101 MDS7006	61579 Blood lancet, single-use	Haemostylet

Class II a (active):

Class	MD-Code	GMDN	Brand
Ila	MD1103	35723 Nerve-locating system, battery-powered Nerve stimulator for nerve and muscle localization	MultiStim ECO MultiStim SWITCH MultiStim SENSOR
Ila	MD1104 MDS7006	58990 Side-notch biopsy gun, single-use Automated Disposable Biopsy System with/ without trocar	CoreCut PrimoCut
Ila	MD1104	22724 Side-notch biopsy gun, reusable Biopsy System: Reusable gun and disposable needles with/ without trocar	DeltaCut

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class II b (non-active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD0101 MDS7006	46383 Peripheral anaesthesia catheter set, non-medicated Peripheral catheters for continuous anaesthesia and analgesia	PlexoLong Cath PlexoLong Cath NRFit® StimuLong Cath StimuLong Cath NRFit® Plexus Cath Plexus Cath NRFit® SonoLong Curl Echo Cath SonoLong Curl Echo Cath NRFit® InfiltraLong Catheter Peripheral standard catheter Peripheral standard catheter NRFit® Peripheral coiled catheter Peripheral coiled catheter NRFit® Peripheral stimulation catheter Peripheral stimulation catheter NRFit® Peripheral coiled stimulation catheter Peripheral coiled stimulation catheter NRFit® Catheter Seldinger technique Catheter Seldinger technique NRFit®
IIb	MD0102 MDS7006	47737 Orthopaedic cement injection cannula Disposable needles for cement injection	Special-Vertebroplasty Cannula acc. To Gangi, Needles/ cannulas/ Trocars for Cemento disposable gun Needles/ cannulas/ Trocars for Cemento reusable gun 1394-Series 1384-Series 1392-Series 1393-Series 1382-Series
IIb	MD0106 MDS7006	46542 Elastomeric infusion pump system	FuserPump FuserPump NRFit®

Class II b (active):

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD 0102 MDS7006	58739 - Radio-frequency ablation system probe cannula, single-use Thermolesion needles, cannulas and trocars for RF-Ablation	RFTL Needle RFTL Needle NRFit® RFTL SONO RFTL Sono NRFit® PulsedRF PulsedRF Sono Thermolesion cannula/ needle Thermolesion cannula/ needle NRFit® RGN cannula/ needle RGN Cannula/ Needle NRFit®
IIb	MD1104	33596 Endoscopic electro-surgical coagulator/cutter, unipolar, reusable Modular HF/SI-System: Rod, Handle, tube, figure	FlowTube HF FlowTube HF-C FlowTube HF RET FlowTube HF-C RET Handle HF Handle HF-C J-Hook Right Angle (90°) 45° angle Needle Spatula Ballpoint Conical 1299-Series

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
			2000-series (standalone, integrated handle)
IIb	MD1104	35732 Rigid endotherapy biopsy forceps, reusable Modular HF/SI-System: Rod, Handle, tube, figure	ErgoForceps ErgoTop biopsy punch, serration biopsy punch biopsy punch, spoon shaped Biopsy spoon forceps with fixation thorn Biopsy punch, spoon shaped, fixation thorn Biopsy Kit 1292-Series
IIb	MD1104	35080 Laparoscopic grasping forceps Modular HF/SI-System: Rod, Handle, tube, figure	ErgoForceps ErgoClamp ErgoTop BABCOCK COLLIN MONTGOMERY KOCHER DE BAKEY MultiTip MARYLAND Universal Claw type DOLPHIN Reservoir Atraumatic OVIDUCT MOUSE TOOTH ALLIGATOR MIXTER ALLIS MAXI GRIP DORSEY MultiTip ENDOCLINCH KELLY AGGRESSIVE RETRACTION DUCKBILL Grasper Kit Scissor Kit Scissor kit MonoTip Clamping Kit 1292-Series 1293-Series
IIb	MD1104	35080 Laparoscopic grasping forceps Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip MARYLAND MonoTip ENDOCLINCH
IIb	MD1104	37148 Laparoscopic sleeve HF and SI Systems:	FlowTube HF FlowTube HF-C 1299-Series

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD1104	38727 General-purpose surgical scissors, reusable Modular HF/SI-System: Rod, Handle, tube, figure	MultiTip METZENBAUM (M, L, S, P) ErgoScissors ErgoTop Dissection SCISSORS curved/ straight Dissection SCISSORS METZENBAUM Hook Type SCISSORS Hooked Scissors METZENBAUM Micro Scissors curved/ straight Peritoneal Scissors curved/ straight Fine Serration Curved Surgical scissors Wondercut Metzenbaum Soft Surgical Spoon Scissor Kit 1292-Series 1293-Series
IIb	MD1104	38727 General-purpose surgical scissors, reusable Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip METZENBAUM M
IIb	MD1104 MDS7006	58949 General-purpose surgical scissors, single-use Modular HF/SI-System: Rod, Handle, tube, figure	MonoTip METZENBAUM L MonoTip METZENBAUM M MonoTip METZENBAUM S MonoTip METZENBAUM P Scissor Kit
IIb	MD1104	36136 Haemostatic knife Modular HF/SI-System: Rod, Handle, tube, figure	FlowTube HF FlowTube HF-C FlowTube HF RET FlowTube HF-C RET Handle HF Handle HF-C 1299-Series 2000-series (standalone, integrated handle)
IIb	MD1104 MDS7006	36136 Haemostatic knife Modular HF/SI-System: Rod, Handle, tube, figure	1299-Series FlowTube HF RET
IIb	MD1104	12726 Needle holder, reusable Modular HF/SI-System: Rod, Handle, tube, figure	ErgoNeedle ErgoSys Needle Holder Kit 1292-Series 1000er series

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class	MD-Code	GMDN	Brand/ variants/ item code group
IIb	MD1104	47829 Surgical instrument handle Handles for Suction-Irrigation/ HF-Systems	EcoGrip Mod ErgoFlex ErgoGrip EcoFlex EcoGrip EcoGrip-M EcoGrip-F FlowSys Eco HF FlowSys Ergo HF FlowSys Twin HF FlowSys HF TipRatchet TipHandle Pistol Handle Lever Valve Valve Handle Trumpet Valve Handle Double Trumpet Valve Handle1292-Series 1293-series 1299-series 1000er-series EcoHF-Sys
IIb	MD1104	11798 Utility forceps, reusable Modular inserts with integrated rod	Endo hook, fan shaped
IIb	MD1104	38661 Rigid endoscopic grasping forceps, reusable MIS-HF-System	ErgoSys Scissor Kit
IIb	MD1104	33596 Endoscopic electrosurgical coagulator/cutter, unipolar, reusable MIS-HF-System: Connection Rods, guide tubes	TipRod Eco TipRod Ergo TipTube ErgoTube

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

Class III:

Class	MD-Code	GMDN	Brand or item code group
III	Cannulas for regional anaesthesia at the central nervous system (epidural, spinal, combined spinal-epidural (CSE))		
	MD0101 MDS7006	58293 - Epidural needle, non-threaded	Tuohy Tuohy SONO Tuohy SURETY® Tuohy NRFit® Tuohy NanoLine SPROTTE SPECIAL SPROTTE® SPECIAL NRFit®
		35212 - Spinal needle, single-use Spinal needle for anaesthesia/analgesia conduction and lumbar puncture	SPROTTE® STANDARD SPROTTE® NanoLine SPROTTE® STANDARD NRFit® SPROTTE® Curved SPROTTE® Curved NRFit® SPROTTE® Tapered SPROTTE® Tapered NRFit® SPROTTE® Sono SPROTTE® Sono NRFit® SPROTTE® STANDARD 2.G SPROTTE® STANDARD 2.G NRFit® SPROTTE® SONO 2.G SPROTTE® SONO 2.G NRFit® SPROTTE® STANDARD SURETY® Crawford/ CauDal Needle Crawford/ CauDal Needle NRFit® Quincke Quincke NRFit® Quincke Sono Quincke Sono NRFit® Quincke SURETY®
III	Cannulas for lumbar puncture and myelography at the central nervous system		
	MD0101 MDS7006	35212 - Spinal needle, single-use Needles for diagnostic lumbar puncture (injection, aspiration)	SPROTTE® STANDARD SPROTTE® NanoLine SPROTTE® STANDARD SONO SPROTTE® STANDARD SURETY® SPROTTE® STANDARD NRFit® Quincke Quincke SONO Quincke NRFit® Quincke SURETY®
III	Cannulas and special cannulas for analgesia at the central nervous system		
	MD0101 MDS7006	35212 - Spinal needle, single-use Spinal needle for anaesthesia/analgesia conduction	Chiba

Annex to the EC Certificate No. 51268-16-02

Revision status: 8

Valid from 2021-02-11 to 2023-03-21

Devices/device categories included in the certificate:

III	Catheter for regional anaesthesia, spinal, epidural at the central nervous system (CNS)		
MD0101 MDS7006	34842 Epidural anaesthesia set, non-medicated 34845 Intrathecal anaesthesia set, non-medicated Spinal and epidural catheters for continuous anaesthesia and analgesia	EpiLong Cath EpiLong Cath NRFit® EpiLong Cath SURETY® CNS standard catheter CNS standard catheter NRFit® CNS coiled catheter CNS coiled catheter NRFit® with adapter to: CNS catheter NRFit® CNS coiled catheter NRFit® CNS catheter SURETY®	

III	Cannulas, Special cannulas and treatment units for navigated and manual brain biopsy		
MD0101 MDS7006	38563 Brain biopsy procedure kit Cannula system for stereotactic and navigated brain biopsy	BrainPro DBZ Sedan	

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-02-11
Notified Body ID-number: 0124

CERTIFICATE

PAJUNK®

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization
PAJUNK GmbH Medizintechnologie

Scope of certification:

Development, manufacturing, contract manufacturing and distribution of sterile and non-sterile, active and non-active, disposable and reusable medical devices

Certified location:

Karl-Hall-Straße 1, 78187 Geisingen, Germany
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51268-Z4-00.

Certificate registration no.:	51268-14-01	Certificate valid from:	2021-03-22
Validity of previous certificate:	2021-03-21	Certificate valid to:	2024-03-21



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-12



Annex to the Certificate No. 51268-14-01

Revision status: 0

valid from 2021-03-22 to 2024-03-21

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	PAJUNK GmbH Medizintechnologie	Karl-Hall-Straße 1 78187 Geisingen Germany	Development, manufacturing, contract manufacturing and distribution of sterile and non- sterile, active and non-active, disposable and reusable medical devices
	at the following locations / at the companies at the following locations		Scope of certification
1.	PAJUNK GmbH Medizintechnologie	Pajunkstr. 1 78187 Geisingen Germany	Development, manufacturing, contract manufacturing and distribution of sterile and non- sterile, active and non-active, disposable and reusable medical devices



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-12