EU Quality Management Certificate

This is to certify that the company

TONTARRA Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

SRN: DE-MF-000005520

Digitally signed by Ceaicovschi Tudor
Date: 2025.10.03 09:03:49 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	448891 MDR2017Q
Certificate ID	1000220878
Effective date	2025-03-06
Expiry date	2027-12-14
Frankfurt am Main,	2025-03-06

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005520
Certificate ID: 1000220878

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Antrum punching
Risk classification:	Ir
Basic-UDI-DI:	405018300000369XW
Intended purpose:	Antrum punches are used to punch holes in hard fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Biopsy curettes
Risk classification:	Ir
Basic-UDI-DI:	405018300000227X9
Intended purpose:	Biopsy curettes are used to scrape endometrial secretions and / or tissue from the uterus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Gallstone scoops
Risk classification:	Ir
Basic-UDI-DI:	405018300000207X3
Intended purpose:	Gallstone scoops are used to remove gallstones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dissectors
Risk classification:	Ir
Basic-UDI-DI:	405018300000206WZ
Intended purpose:	Dissectors are used to separate soft tissue or body structures from each other.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Surgical spoon
Risk classification:	Ir
Basic-UDI-DI:	405018300000394XV 405018300000289XX 405018300000394XV 405018300000408XF 405018300000422X9
Intended purpose:	A surgical spoon is used to scrape out or remove tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Chisel
Risk classification:	Ir
Basic-UDI-DI:	405018300000135X3 405018300000136X5 405018300000386XW 405018300000510X7
Intended purpose:	A surgical instrument used to cut or contour bone.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005520
Certificate ID: 1000220878

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Gouge
Risk classification:	Ir
Basic-UDI-DI:	405018300000292XL
Intended purpose:	Gouges are used to separate or to work hard tissue or bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Punching
Risk classification:	Ir
Basic-UDI-DI:	405018300000395XX
Intended purpose:	An ear punch is designed to punch holes in bone and hard tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Osteotome blades
Risk classification:	Ir
Basic-UDI-DI:	405018300000293XN
Intended purpose:	A device that is an interchangeable component of the orthopaedic osteotome and acts as a cutting blade.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Elevators
Risk classification:	Ir
Basic-UDI-DI:	405018300000353XF
Intended purpose:	Elevators of the product group Elevators, others are used to lift and position tissue and organs.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Elevators
Risk classification:	Ir
Basic-UDI-DI:	405018300000389Y4
Intended purpose:	Elevators for the ENT area are used to lift and position tissue, suture material and nerves.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Elevators
Risk classification:	Ir
Basic-UDI-DI:	405018300000290XG
Intended purpose:	Elevators for orthopaedics are used to lift and dissect bones, tissue and nerves. They are also used to clean and scrape bones and to expose fractures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Elevators
Risk classification:	Ir
Basic-UDI-DI:	405018300000349XQ
Intended purpose:	Elevators are used to lift and position tissue and nerves.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Enucleators
Risk classification:	Ir
Basic-UDI-DI:	405018300000339XM
Intended purpose:	Enucleators are used to evacuate intact tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Thread catcher
Risk classification:	Ir
Basic-UDI-DI:	405018300000146X8
Intended purpose:	Thread catchers are used to catch / hold the sewing thread and push the knot.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Fixation instrument
Risk classification:	Ir
Basic-UDI-DI:	405018300000557XZ
Intended purpose:	Fixation instruments are used to fix tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Flat drill
Risk classification:	Ir
Basic-UDI-DI:	405018300000509XN
Intended purpose:	Flat drills are used for drilling shallow cavities and for drilling into cartilage

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Milling cutter
Risk classification:	Ir
Basic-UDI-DI:	405018300000327XE
Intended purpose:	Milling cutters are used for further processing of drilled holes.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Implatation fork
Risk classification:	Ir
Basic-UDI-DI:	405018300000201WP
Intended purpose:	Forks are used to hold and lift fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tissue claw
Risk classification:	Ir
Basic-UDI-DI:	405018300000164XA
Intended purpose:	Fabric claws are used to hold fabric in place.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tick
Risk classification:	Ir
Basic-UDI-DI:	405018300000187XN
Intended purpose:	Hooks are used to separate or expose tissue from other anatomical parts.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Hand drill
Risk classification:	Ir
Basic-UDI-DI:	405018300000325XA
Intended purpose:	Hand drills are used to drill holes in bones using a drill.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Chisel handle
Risk classification:	Ir
Basic-UDI-DI:	405018300000507XJ
Intended purpose:	Handpieces are attached to the proximal end of a surgical instrument.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sphenoidal punch
Risk classification:	Ir
Basic-UDI-DI:	405018300000361XE
Intended purpose:	Cuneiform punches are designed to punch holes in bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bone files
Risk classification:	Ir
Basic-UDI-DI:	405018300000303WY
Intended purpose:	Bone files are used to smooth, grind or shorten bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Surgical punch
Risk classification:	Ir
Basic-UDI-DI:	405018300000295XS
Intended purpose:	A surgical punch for bones is intended to punch holes in bones and hard tissue and remove tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cartilage punch
Risk classification:	Ir
Basic-UDI-DI:	405018300000304X2
Intended purpose:	Cartilage files are used for smoothing, grinding and shortening cartilage tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Curettes
Risk classification:	Ir
Basic-UDI-DI:	405018300000137X7 405018300000340X6 405018300000342XA 405018300000396XZ 405018300000420X5
Intended purpose:	Curettes are designed for scraping, shaping and cleaning skin, tissue or bone.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Micro-instruments
Risk classification:	Ir
Basic-UDI-DI:	405018300000088XK
Intended purpose:	Knives are used for cutting various fabrics.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Myoma drill
Risk classification:	Ir
Basic-UDI-DI:	405018300000250X4
Intended purpose:	Myoma drills are used to stabilise and manipulate fibroids.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Needles
Risk classification:	Ir
Basic-UDI-DI:	405018300000338XK
Intended purpose:	Needles are used to puncture tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nail drill
Risk classification:	Ir
Basic-UDI-DI:	405018300000324X8
Intended purpose:	Nail Drills are used for puncturing and drilling of finger and toenails.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Obturators
Risk classification:	Ir
Basic-UDI-DI:	405018300000504XC
Intended purpose:	Obturators are used for the atraumatic insertion of sockets at the surgical site.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ear curettes
Risk classification:	Ir
Basic-UDI-DI:	405018300000388Y2
Intended purpose:	Ear curettes are intended to scrape, form and clean skin, tissue and bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ear loops
Risk classification:	Ir
Basic-UDI-DI:	405018300000384XS
Intended purpose:	Ear loops are used to cut off tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Osteotomes
Risk classification:	Ir
Basic-UDI-DI:	405018300000291XJ
Intended purpose:	Orthopaedic osteotomes are used to shape and model bone material.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Preperation electrode
Risk classification:	Ir
Basic-UDI-DI:	405018300000248XH 405018300000482XT
Intended purpose:	Preparation electrodes (cold electrodes) are designed to separate the myoma from the surrounding myometrium and to dilate stenotic tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Raspatorium
Risk classification:	Ir
Basic-UDI-DI:	405018300000377XV
Intended purpose:	Rasps for the middle ear are used to smooth, shape and clean bony structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rasps
Risk classification:	Ir
Basic-UDI-DI:	405018300000368XU
Intended purpose:	Rasps for the nose are used to smooth, form and clean bony structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rasps
Risk classification:	Ir
Basic-UDI-DI:	405018300000301WU
Intended purpose:	Graters for bones are used to flatten, shape and clean bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Revolution punching
Risk classification:	Ir
Basic-UDI-DI:	405018300000296XU
Intended purpose:	Revolution punches are designed to punch holes in bone and hard tissue and remove the tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rongeurs
Risk classification:	Ir
Basic-UDI-DI:	405018300000317XB
Intended purpose:	Rongeurs are designed to punch holes in cartilage and remove the tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissor punching
Risk classification:	Ir
Basic-UDI-DI:	405018300000413X8
Intended purpose:	Scissor punches are used to punch holes in soft fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Twist drill
Risk classification:	Ir
Basic-UDI-DI:	405018300000326XC
Intended purpose:	Twist drills are used to drill holes in bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sternum chisel
Risk classification:	Ir
Basic-UDI-DI:	405018300000508XL
Intended purpose:	Sternum chisels are used to split the breastbone.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Plunger
Risk classification:	Ir
Basic-UDI-DI:	405018300000302WW
Intended purpose:	Plungers are used to compact or wedge structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Trephines
Risk classification:	Ir
Basic-UDI-DI:	405018300000421X7
Intended purpose:	Trephines are used to take tissue samples.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Trocars
Risk classification:	Ir
Basic-UDI-DI:	405018300000158XF
Intended purpose:	Trocars are used to gain access to the surgical site.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Uterine curettes
Risk classification:	Ir
Basic-UDI-DI:	405018300000229XD
Intended purpose:	Uterine curettes are used to scrap tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Fistula probes
Risk classification:	Ir
Basic-UDI-DI:	405018300000156XB
Intended purpose:	Fistula probes are used in abnormal body passages or connection (fistulas).

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Gall duct probes
Risk classification:	Ir
Basic-UDI-DI:	405018300000222WX
Intended purpose:	Gall duct probes are used to explore the bile duct.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Goitre probes/ hollow probes
Risk classification:	Ir
Basic-UDI-DI:	405018300000027WX 405018300000145X6
Intended purpose:	Hollow probes / goiter probes are used to form a guide

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Probes
Risk classification:	Ir
Basic-UDI-DI:	405018300000417XG
Intended purpose:	Meniscus probes are used to examine the inside of the joint and for therapeutic interventions in the joint.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Probes
Risk classification:	Ir
Basic-UDI-DI:	405018300000157XD
Intended purpose:	Probes are intended to reach difficult accessible places or remote locations to examine the place.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Uterine depressors
Risk classification:	Ir
Basic-UDI-DI:	405018300000240WZ
Intended purpose:	Uterine depressors are used to move or retract the uterus from its position to visualise other structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Uterine probes
Risk classification:	Ir
Basic-UDI-DI:	405018300000241X3
Intended purpose:	Uterine probes are used to examine and explore the uterus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Applicators for clips
Risk classification:	Ir
Basic-UDI-DI:	405018300000143X2 405018300000272XE
Intended purpose:	Applikatoren für Clips werden dazu verwendet Clips zu halten, sie anzubringen bzw. zu applizieren und wieder zu entfernen.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Applicator
Risk classification:	Ir
Basic-UDI-DI:	405018300000139XB
Intended purpose:	Applicators are used to place and secure cerclage wire

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Contact pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000139XB
Intended purpose:	Applicators are used to place and secure haemostatic clips.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Extractors
Risk classification:	Ir
Basic-UDI-DI:	405018300000423XB
Intended purpose:	Extractors are used to catch varices.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ring applicators
Risk classification:	Ir
Basic-UDI-DI:	405018300000479Y6 405018300000480XP
Intended purpose:	Ring applicators are used to position the silicone rings to clamp the woman's fallopian tubes.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Screwdriver / extraction bolt
Risk classification:	Ir
Basic-UDI-DI:	405018300000332X7 405018300000333X9
Intended purpose:	Screwdriver for bones are used to introduce or remove surgical screws.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Underbanding needles/ palatal needles
Risk classification:	Ir
Basic-UDI-DI:	405018300000140WU 405018300000142WY
Intended purpose:	The ligature needle holds the surgical thread over which a ligature is performed.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Guide needles
Risk classification:	Ir
Basic-UDI-DI:	405018300000029X3
Intended purpose:	The Redon guide needle is used to guide the plastic drain from the inside of the body through the skin.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Thread catcher
Risk classification:	Ir
Basic-UDI-DI:	405018300000149XE 405018300000513XD 405018300000528XS
Intended purpose:	Thread catchers are used to catch the suture material.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Thread guiding pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000514XF
Intended purpose:	Suture guide forceps are used to close wounds after laparoscopic procedures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Thread fork
Risk classification:	Ir
Basic-UDI-DI:	405018300000512XB
Intended purpose:	Thread forks are used to knot the thread.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Suture holding forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000568Y6
Intended purpose:	Suture holding forceps are used for wound closure after surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Thread holding pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000148XC
Intended purpose:	Thread holding pliers are used to close wounds after laparoscopic procedures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Management tool
Risk classification:	Ir
Basic-UDI-DI:	405018300000535XP
Intended purpose:	Guides for drill bits are used to direct or guide drill bits in order to position them.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Knot guide / knot slider
Risk classification:	Ir
Basic-UDI-DI:	405018300000080X3 405018300000526XN 405018300000529XU
Intended purpose:	Knot guides / knot pushers are used to push seam knots to the point of suitable seam tension.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Needle
Risk classification:	Ir
Basic-UDI-DI:	405018300000511X9
Intended purpose:	Needles for suturing the fascia are used to close wounds after laparoscopic procedures

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Paracentesis needles
Risk classification:	Ir
Basic-UDI-DI:	405018300000378XX
Intended purpose:	Paracentesis needles are used to pierce the eardrum.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Reverdin needles
Risk classification:	Ir
Basic-UDI-DI:	405018300000141WW
Intended purpose:	Reverdin needles are used to pierce thick skin or firm tissue and sew over an inserted thread

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Abortion forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000225X5
Intended purpose:	Abortion forceps are used to grasp, hold and secure or remove the ovaries and placenta pieces.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Baby Duckbill punches
Risk classification:	Ir
Basic-UDI-DI:	405018300000351XB
Intended purpose:	Foreign body grasping forceps / foreign body forceps are used to grasp, hold and remove foreign bodies.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Chalazion tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000536XR
Intended purpose:	Chalazion forceps are used to reverse the eyelid and expose chalazion for drainage and removal.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cholangiography forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000548XY
Intended purpose:	Cholangiography forceps are used to insert the cholangiography catheter into the bile duct in order to inject the contrast solution.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cilia tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000403X5
Intended purpose:	Cilia tweezers are used to grip or manipulate the eyelashes.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Intestinal/tissue forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000210WQ
Intended purpose:	Intestinal/Tissue grasping forceps are used to grasp and / or compress internal intestinal structures or tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Gripper tongs
Risk classification:	Ir
Basic-UDI-DI:	405018300000003WH
Intended purpose:	The grasping tongs are used for endoscopic diagnosis and treatment in urology.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Wire cutters
Risk classification:	Ir
Basic-UDI-DI:	405018300000299Y2
Intended purpose:	Wire pliers / wire crimping pliers / wire clamping pliers / locking pliers are used to hold, tighten, cut and / or twist surgical wire.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000003WH 405018300000538XV 405018300000547XW
Intended purpose:	Gripping tongs are used to grip and hold fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Flat nose pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000298XY
Intended purpose:	Flat nose pliers / parallel nose pliers are used to bend and cut wires.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Foreign body forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000171X7 405018300000254XC
Intended purpose:	Foreign body grasping forceps / foreign body forceps are used to grasp, hold and remove foreign bodies.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000171X7 405018300000254XC 405018300000298XY 405018300000351XB 405018300000371XH 405018300000374XP 405018300000414XA 405018300000549Y2 405018300000550XK 405018300000551XM 405018300000552XP 405018300000569Y8 405018300000570XR 405018300000571XT 405018300000572XV
Intended purpose:	Foreign body grasping forceps / foreign body tongs are used to grasp, hold and remove foreign bodies.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Foreign body lever
Risk classification:	Ir
Basic-UDI-DI:	405018300000390XM
Intended purpose:	Foreign body levers are used to loosen foreign bodies in the ear.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vascular forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000166XE
Intended purpose:	Vascular forceps are used to grip and hold delicate tissue atraumatically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Iris tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000404X7
Intended purpose:	Iris forceps are used to grasp, hold or manipulate tissues of the eye or surrounding tissues.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Capsule forceps

Risk classification:	Ir
Basic-UDI-DI:	405018300000266XK
Intended purpose:	Capsule graspers are used to grip, hold and manipulate soft tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Capsule tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000543XN
Intended purpose:	Capsule forceps are used to hold lens capsules during surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Catheter insertion instruments
Risk classification:	Ir
Basic-UDI-DI:	405018300000268XP
Intended purpose:	Catheter insertion instruments are used to insert and position catheters in the urinary tract.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Catheter insertion forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000375XR
Intended purpose:	Catheter insertion forceps are used to grip and hold the endotracheal tube during intubation or to remove foreign bodies from the airways.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Laryngeal polyp forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000373XM
Intended purpose:	Laryngeal polyp forceps are used to remove polyps from the vocal cords.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Clamp holder
Risk classification:	Ir
Basic-UDI-DI:	405018300000214WY
Intended purpose:	Clamp holders are used to hold the clamp in position.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Clamp closing pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000211WS 405018300000539XX
Intended purpose:	Clamp closing pliers are used to close clamps.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bone holding forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000306X6
Intended purpose:	Bone holding forceps are used to grasp and hold bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bone splinter forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000297XW
Intended purpose:	Bone splitting forceps are used to cut bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cartilage grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000316X9
Intended purpose:	Cartilage grasping forceps are used to grasp and hold cartilage

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cartilage crushing
Risk classification:	Ir
Basic-UDI-DI:	405018300000334XB
Intended purpose:	Cartilage crushers are used to crush pieces of cartilage that have been removed.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Laryngoscope spoon forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000372XK
Intended purpose:	Laryngoscope spoon forceps are used to grip, hold and manipulate soft tissue / anatomical structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Spoon tongs / ear tongs

Risk classification:	Ir
Basic-UDI-DI:	405018300000383XQ
Intended purpose:	Spoon tongs / ear tongs are used to grip, manipulate, compress or pull fabric, equipment or accessories.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Marker
Risk classification:	Ir
Basic-UDI-DI:	405018300000425XF
Intended purpose:	Markers enable precise marking of (skin) flaps for excision

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Meniscus grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000415XC
Intended purpose:	Meniscus grasping forceps are used to grip, hold and compress the meniscus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Needle holder
Risk classification:	Ir
Basic-UDI-DI:	405018300000144X4 405018300000337XH 405018300000352XD
Intended purpose:	Needle holders are designed to hold the sewing needles firmly during sewing.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nail extrusion forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000540XG
Intended purpose:	Nail extraction forceps are used to split and remove ingrown nails.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Micro-tying tweezers / suture tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000147XA 405018300000406XB
Intended purpose:	Suture tweezers / micro-tying tweezers are used to grip and hold suture material.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ear and nose tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000380XJ

Intended purpose:	Ear and nose forceps are used to grasp or hold tissue on the nose or ear.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ear polyp forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000381XL
Intended purpose:	Ear polyp forceps are used to grasp, hold and remove soft tissue or polyps in the ear.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Organ grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000167XG
Intended purpose:	Organ grasping forceps are used to grasp organs atraumatically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Patella forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000541XJ
Intended purpose:	Patella forceps are used to grip and hold the patella.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	PE pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000160X2
Intended purpose:	PE forceps are used for the endoscopic removal of tissue samples.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tweezers / Tissue grasping tweezers / Hook tweezers / Fixation tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000165XC 405018300000183XE 405018300000186XL 405018300000336XF 405018300000405X9 405018300000407XD
Intended purpose:	Tweezers / tissue grasping tweezers / hook tweezers / fixing tweezers are used to grasp, manipulate, squeeze, pull or connect tissue, materials or accessories.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000546XU

Intended purpose:	Forceps for changing the valves are used to change the valves.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Haemorrhoidal forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000237XC
Intended purpose:	Polyp forceps / polyp forceps / haemorrhoidal forceps are used to grasp, hold and remove polyps in the uterus

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Polyp forceps / polyp forceps / nasal forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000237XC 405018300000365XN 405018300000382XN 405018300000537XT
Intended purpose:	Polyp forceps / polyp forceps / nasal forceps are used to grasp, hold and remove polyps.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pyloric spreader
Risk classification:	Ir
Basic-UDI-DI:	405018300000545XS
Intended purpose:	Pyloric spreaders are used to separate the pylorus or other gastrointestinal structures from adjacent structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Reduction forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000305X4 405018300000307X8
Intended purpose:	Reduction forceps are used to hold and reposition bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sponge forceps / grain forceps / swab forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000161X4 405018300000162X6 405018300000163X8
Intended purpose:	Sponge forceps / grain forceps / swab forceps are used to grip surgical sponges.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tendon pulling forceps / tendon grasping forceps / instruments
Risk classification:	Ir
Basic-UDI-DI:	405018300000313X3

	405018300000314X5
Intended purpose:	Tendon tunneling forceps / Tendon grasping forceps / instruments are used to grasp, hold, pull and guide tendons.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Side cutters / bolt cutters / head cutters
Risk classification:	Ir
Basic-UDI-DI:	405018300000300WS
Intended purpose:	Side cutting pliers / bolt cutting pliers / head cutting pliers are used to cut orthopedic wires or pins.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Septum straightening forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000363XJ
Intended purpose:	Septum straightening forceps / septum crimping forceps are used to grip and straighten the septum.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sinus clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000163X8
Intended purpose:	Sinus clamps are used to grip surgical sponges.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sinuscopy forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000364XL
Intended purpose:	Sinuscopy forceps are used to grasp, hold and remove polyps and to open the maxillary, frontal and sphenoid sinuses.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Splinter tweezers
Risk classification:	Ir
Basic-UDI-DI:	405018300000174XD
Intended purpose:	Splinter tweezers are used to grasp, hold and remove small foreign bodies.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Biopsy forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000159XH 405018300000212WU 405018300000232X2 405018300000252X8 405018300000256XG 405018300000346XJ 405018300000347XL 405018300000542XL
Intended purpose:	Rigid biopsy forceps are used for the endoscopic removal of tissue samples.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Stone grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000257XJ
Intended purpose:	Stone grasping forceps are used for endoscopic diagnosis and treatment in urology.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tampon forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000362XG
Intended purpose:	Tampon forceps are used to apply gauze bandages.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tenaculum grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000234X6
Intended purpose:	Tenaculum forceps are used for grasping and holding cervical tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tonsil forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000359XT
Intended purpose:	Tonsil forceps are intended to hold the tonsil.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tumour grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000175XF
Intended purpose:	Tumour grasping forceps are used to grasp, hold and remove the tumour.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tunnelling pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000318XD
Intended purpose:	Tunnelling pliers are used to grip and hold vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Uterine grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000235X8 405018300000236XA 405018300000238XE
Intended purpose:	Uterine grasping forceps are used to lift the vaginal wall and to grasp, hold and remove vaginal overgrowths, polyps and malignant diseases.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Uterine clamp forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000226X7
Intended purpose:	Uterine clamp forceps are used to grip and clamp tissue in the uterus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cotton swabs
Risk classification:	Ir
Basic-UDI-DI:	405018300000176XH
Intended purpose:	Cotton swabs are used to hold a plaster at their distal end to clean or apply a substance to superficial wounds or body orifices.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dental forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000544XQ
Intended purpose:	Dental forceps are used to grip a dressing that is applied orally.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Gallstone forceps
Risk classification:	Ir

Basic-UDI-DI:	405018300000208X5
Intended purpose:	Forceps for the gallbladder are designed to grasp or manipulate the gallstones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Birth forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000223WZ
Intended purpose:	Obstetric forceps are used to grasp the newborn's head and facilitate the birth process.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Lung grasping forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000168XJ
Intended purpose:	Forceps for the lung are designed to grasp, manipulate or support the lung atraumatically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Kidney stone forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000261X9
Intended purpose:	Kidney forceps are designed to grasp and remove kidney stones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tonsil forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000359XT
Intended purpose:	Tonsil forceps are intended to hold the tonsil.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pliers for bones
Risk classification:	Ir
Basic-UDI-DI:	405018300000308XA 405018300000322X4 405018300000370XF 405018300000418XJ
Intended purpose:	Pliers for bones are used for gripping, cutting or breaking bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pliers

Risk classification:	Ir
Basic-UDI-DI:	405018300000239XG
Intended purpose:	IUD removal forceps / IUD removal instruments are used to remove IUDs.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Anastomosis clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000215X2 405018300000279XU
Intended purpose:	Anastomosis clamps are used to grip and temporarily close blood vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Aneurysm clips
Risk classification:	Ir
Basic-UDI-DI:	405018300000275XL
Intended purpose:	Aneurysm clips are used to grip blood vessels and completely block the blood flow.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Aortic clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000277XQ 405018300000280XD
Intended purpose:	Aortic clamps are used to grip and compress large vessels with thick and dense walls.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Artery clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000178XM
Intended purpose:	Haemostatic forceps are used to grip and compress arteries.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Auricular clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000285XP
Intended purpose:	Auricular clamps are used to grip the atrium while a suture is placed or bleeding is stopped.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bronchus clamps
Risk classification:	Ir

Basic-UDI-DI:	405018300000185XJ
Intended purpose:	Bronchus clamps are used to grip the bronchi and compress them atraumatically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bulldog clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000271XC
Intended purpose:	Bulldog clamps are used to temporarily compress vessels atraumatically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Coarctation clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000180X8 405018300000281XF 405018300000283XK
Intended purpose:	Coarctation clamps are used to grip and compress the aorta.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pressure clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000179XP
Intended purpose:	Pressure clamps are used to grip blood vessels and control blood flow.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bowel clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000213WW
Intended purpose:	Bowel clamps are used to grip the bowel and temporarily close the end of the bowel.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Drum clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000169XL 405018300000518XP
Intended purpose:	Seizing clamps / thoracic clamps are used to grasp and compress tissues.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bile duct clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000209X7

Intended purpose:	Bile duct clamps are used to grasp and clamp bile ducts.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000177XK 405018300000274XJ
Intended purpose:	Vascular clamps / paediatric vascular clamps / peripheral vascular clamps / dissecting clamps / ligature clamps / aorta ligature clamps / atrauma clamps are used to grip vessels and compress them for temporary haemostasis

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Haemorrhoid clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000516XK
Intended purpose:	Haemorrhoid clamps are used to grip and hold the haemorrhoids in place.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Hysterectomy clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000233X4
Intended purpose:	Hysterectomy clamps are used to grasp and compress tissue and structures of the uterus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Iliac clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000523XG
Intended purpose:	Iliac clamps are used to grip and compress the iliac arteries.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Circumcision device
Risk classification:	Ir
Basic-UDI-DI:	405018300000263XD
Intended purpose:	Circumcision clamps are used to compress the foreskin of the penis during circumcision and to control bleeding.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bone holding clamps
Risk classification:	Ir

Basic-UDI-DI:	405018300000309XC
Intended purpose:	Bone holding clamps are used to grasp bone and hold them in position.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scalp clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000348XN
Intended purpose:	Scalp clamps are used to grip the scalp of children to facilitate delivery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ligature clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000184XG
Intended purpose:	Ligature clamps are used to grip and fix tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Mylohyoid muscle clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000276XN
Intended purpose:	Mylohyoid muscle clamps are used to grip and compress the mylohyoid muscle.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Renal pedicle clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000262XB
Intended purpose:	Renal pedicle clamps are used to grip and compress the renal pedicle.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Peritoneal clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000217X6
Intended purpose:	Peritoneal clamps are used to grip and compress the peritoneum.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Profunda clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000278XS
Intended purpose:	Profunda clamps are used to grip and compress vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ramus clamps

Risk classification:	Ir
Basic-UDI-DI:	405018300000191XD
Intended purpose:	Ramus clamps are used to grip and compress the mandibular ramus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Anastomosis clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000216X4
Intended purpose:	Rectal anastomosis clamps are used to grip tissue atraumatically in order to stop bleeding.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Anastomosis clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000216X4
Intended purpose:	Rectal clamps are used to atraumatically grasp, connect, compress or support the rectum, the rectal valves or the anal canal.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tendon interlacing clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000315X7
Intended purpose:	Tendon interlacing clamps are used to hold and pull on injured tendons.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tobacco pouch seam clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000519XR
Intended purpose:	Tobacco pouch seam clamps are used to grip and fix the tobacco pouch seam.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tangential clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000284XM
Intended purpose:	Tangential clamps are used to regulate the blood flow through the main vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	URO-TANGENTIAL clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000267XM

Intended purpose:	URO-TANGENTIAL clamps are used to grip and compress urine-forming and urine-draining tissues and structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vasectomy clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000265XH
Intended purpose:	Vasectomy clamps are used to grip and fix the vas deferens during vasectomy.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vena cava clamps
Risk classification:	Ir
Basic-UDI-DI:	405018300000265XH
Intended purpose:	Vena cava clamps are used to grip the vena cava and regulate the blood flow.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vein strippers
Risk classification:	Ir
Basic-UDI-DI:	405018300000287XT 405018300000428XM
Intended purpose:	Vein strippers are used to pull veins or remove them for transplantation.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tendon strippers
Risk classification:	Ir
Basic-UDI-DI:	405018300000330X3
Intended purpose:	Tendon strippers are used to pull tendons or remove them for transplantation.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bone rongeur forc
Risk classification:	Ir
Basic-UDI-DI:	405018300000310WV
Intended purpose:	Bone rongeur forceps are used to cut through small bones and remove larger bones and bone fragments

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Amniotome
Risk classification:	Ir

Basic-UDI-DI:	405018300000224X3
Intended purpose:	An amniotome is used to cut or tear the membrane surrounding the foetus.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Zygomatic bone reamers
Risk classification:	Ir
Basic-UDI-DI:	405018300000331X5
Intended purpose:	Zygomatic reamers are used to pierce the zygomatic arch and sew it over a wire.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Orthopaedic reamers / bone reamers
Risk classification:	Ir
Basic-UDI-DI:	405018300000294XQ
Intended purpose:	Orthopaedic reamers / bone reamers are designed to form and resect holes in bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Puncture needles
Risk classification:	Ir
Basic-UDI-DI:	405018300000356XM
Intended purpose:	Puncture needles are used to puncture tissue in order to take tissue samples.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Adenotomes
Risk classification:	Ir
Basic-UDI-DI:	405018300000358XR
Intended purpose:	Adenotomes are used to remove severely enlarged palatine tonsils (tonsils).

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Amputation saws
Risk classification:	Ir
Basic-UDI-DI:	405018300000129X8
Intended purpose:	Amputation saws are used to saw through bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bayonet knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000092XA
Intended purpose:	Bayonet knives are used to cut through fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Banana knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000094XE
Intended purpose:	Banana knives are used to cut through fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cartilage resection knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000416XE
Intended purpose:	Cartilage resection knives are used to cut through cartilage.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Episiotomy scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000122WS
Intended purpose:	Episiotomy scissors are used for cutting the perineum and posterior vaginal wall.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Knife
Risk classification:	Ir
Basic-UDI-DI:	405018300000385XU
Intended purpose:	The instrument is used for incisions in the ENT area (throat/nose/ear).

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tonsil knife
Risk classification:	Ir
Basic-UDI-DI:	405018300000360XC
Intended purpose:	The tonsil knife is used to surgically remove the palatine tonsils.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dermatomes
Risk classification:	Ir
Basic-UDI-DI:	405018300000100WG
Intended purpose:	Dermatomes are used to obtain uniform skin flaps that serve as grafts. Dermatomes are also used to cut out small skin lesions.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Saw blades
Risk classification:	Ir
Basic-UDI-DI:	405018300000134WZ
Intended purpose:	The blade provides the cutting edge for cutting materials or tissues.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Blade
Risk classification:	Ir
Basic-UDI-DI:	405018300000101WJ
Intended purpose:	The blade is used as cutting edge for the extraction of even skin flaps or to remove smaller skin lesions.
Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cutting pliers
Risk classification:	Ir
Basic-UDI-DI:	405018300000311WX
Intended purpose:	The cutting pliers for ribs are used to cut through bones and ribs.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Wire saws
Risk classification:	Ir
Basic-UDI-DI:	405018300000131WT
Intended purpose:	Wire saws are used to cut smoothly through boiling.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Wire cutters
Risk classification:	Ir
Basic-UDI-DI:	405018300000127X4
Intended purpose:	Wire cutters are used for cutting wire.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Suture cutter
Risk classification:	Ir
Basic-UDI-DI:	405018300000107WW
Intended purpose:	Suture cutter are used to endoscopically cut the sewing thread.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Fistula knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000090X6
Intended purpose:	Fistula knives are used for tissue dissection and making incision.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Fistula scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000124WW
Intended purpose:	Fistula scissors are used for cutting fistulas.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vascular scissors

Risk classification:	Ir
Basic-UDI-DI:	405018300000108WY
	405018300000117WZ
Intended purpose:	Vascular scissors are used for cutting vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Hook knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000095XG
Intended purpose:	Hook knives are used to cut through fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Hook scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000350X9
Intended purpose:	Hook scissors are used to cut tissue endoscopically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Micro scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000335XD
Intended purpose:	Capsule shears are used to cut capsule structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cartilage scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000109X2
Intended purpose:	Cartilage scissors are used to cut cartilage tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ligature scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000104WQ
Intended purpose:	Ligature scissors are used to cut suture or ligature material.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Lung flap and rectal scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000118X3
Intended purpose:	Lung flap and rectal scissors are used to cut or dissect tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Meniscus knives

Risk classification:	Ir
Basic-UDI-DI:	405018300000091X8 405018300000093XC
Intended purpose:	Meniscus knives are used to cut meniscus fragments.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Amputation knife
Risk classification:	Ir
Basic-UDI-DI:	405018300000089XM
Intended purpose:	Knives for amputation are intended for the amputation of limbs.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Micro laryngeal scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000125WY
Intended purpose:	Micro laryngeal scissors are used to make fine incisions in laryngeal surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Micro tumour scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000106WU
Intended purpose:	Micro tumour scissors are used to separate tumours from the surrounding tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Myoma knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000242X5
Intended purpose:	Myoma knives are used to cut cone-shaped tissue from the cervix.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nose saws
Risk classification:	Ir
Basic-UDI-DI:	405018300000130WR
Intended purpose:	Nose saws are used to cut bone tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nasals scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000112WP
Intended purpose:	Nasals scissors are used for cutting or dissecting tissue of the nose.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ear scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000113WR
Intended purpose:	Ear scissors are used to cut or dissect tissue in the ear.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rhinoplasty knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000085XD
Intended purpose:	Rhinoplasty knives are used to make incisions.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissors for the eye
Risk classification:	Ir
Basic-UDI-DI:	405018300000110WK
Intended purpose:	Scissors for the eye are used to cut structures / tissues on the eye and / or the iris.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissors for the gynaecology
Risk classification:	Ir
Basic-UDI-DI:	405018300000123WU
Intended purpose:	Scissors for the gynaecology are used to cut tissues and structures in the female reproductive system.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissors for plastic surgery
Risk classification:	Ir
Basic-UDI-DI:	405018300000424XD
Intended purpose:	Plastic surgery scissors are used for cutting in shape-altering or reconstructive procedures

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tonsil scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000114WT
Intended purpose:	Tonsil scissors are used to remove the tonsils through cutting.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissor attachments
Risk classification:	Ir
Basic-UDI-DI:	405018300000126X2
Intended purpose:	Scissor attachments are used to cut tissue endoscopically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000105WS 405018300000119X5
Intended purpose:	Scissors are used for cutting or preparing different tissues or materials.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Tendon scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000111WM
Intended purpose:	Tendon scissors are used for cutting tendons.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	BALLENGER septum knife
Risk classification:	Ir
Basic-UDI-DI:	405018300000086XF
Intended purpose:	Septum knives are used to cut cartilage and soft tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sickle knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000096XJ
Intended purpose:	Sickle knives are used to cut through fabric.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scalpel knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000084XB
Intended purpose:	Scalpel knives are used to sharply cut through tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Stricture knives
Risk classification:	Ir
Basic-UDI-DI:	405018300000098XN
Intended purpose:	Stricture knives are used to widen the urethra by making incisions.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Trigeminal scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000116WX
Intended purpose:	Trigeminal scissors are used to cut the trigeminal nerve.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Conversion instrument
Risk classification:	Ir
Basic-UDI-DI:	405018300000419XL
Intended purpose:	Conversion instrument are used to guide flexible wire saws around bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ureteral slitting scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000253XA
Intended purpose:	Ureteral slitting scissors are used to slit open urethral strictures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Urethrotomes
Risk classification:	Ir
Basic-UDI-DI:	405018300000428XM 405018300000499YC
Intended purpose:	Urethrotomes are used to slit open urethral strictures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dental scissors
Risk classification:	Ir
Basic-UDI-DI:	405018300000115WV
Intended purpose:	Dental scissors are used to cut or prepare gums.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Aortic hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000270XA
Intended purpose:	Aortic hooks are used to exert traction on the aorta.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Atrial hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000269XR
Intended purpose:	Atrial hooks are used to grip and retract the atria.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Abdominal spatulas
Risk classification:	Ir
Basic-UDI-DI:	405018300000203WT
Intended purpose:	Abdominal spatulas are used to hold back soft tissue organs.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bladder spatula
Risk classification:	Ir
Basic-UDI-DI:	405018300000204WV
Intended purpose:	Bladder spatulas are used to grasp and withdraw the bladder.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Alar Retractor
Risk classification:	Ir
Basic-UDI-DI:	405018300000527XQ
Intended purpose:	The LATERA® Alar retractor is used with LATERA® implants in nasal surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dilators
Risk classification:	Ir
Basic-UDI-DI:	405018300000259XN 405018300000428XM
Intended purpose:	Dilators for the choledochal duct are designed to examine or dilate the bile duct.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dilators
Risk classification:	Ir
Basic-UDI-DI:	405018300000357XP 405018300000401WZ
Intended purpose:	Dilators are used to dilate the nephrostomy tract.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Retractors
Risk classification:	Ir
Basic-UDI-DI:	405018300000354XH
Intended purpose:	Endo retractors are used to hold disturbing structures out of the surgical site.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Exploratory hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000343XC

Intended purpose:	Exploratory hooks are used to explore nerve tissue and the vascular system.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Fistula hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000197XR
Intended purpose:	Fistula hooks are used to grip, stabilise and retract sensitive soft tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Retractor
Risk classification:	Ir
Basic-UDI-DI:	405018300000195XM 405018300000200WM
Intended purpose:	Flexible retractors are used to separate tissue or other anatomical parts.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nerve and vascular hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000345XG
Intended purpose:	Vessel hooks are used to grip and retract vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Skin hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000199XV
Intended purpose:	Skin hooks are used to fix tissue or to apply traction to the skin.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Knee hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000323X6
Intended purpose:	Knee hooks are used to grip fabric and pull it back at a right angle.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Bone lever
Risk classification:	Ir
Basic-UDI-DI:	405018300000312WZ
Intended purpose:	Bone lever are used to lift and position bones.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Lid retractors
Risk classification:	Ir
Basic-UDI-DI:	405018300000517XM
Intended purpose:	Lid retractors are used to grip and retract the upper eyelid and eyelashes.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Lung spatula
Risk classification:	Ir
Basic-UDI-DI:	405018300000288XV
Intended purpose:	Lung spatulas are used to manipulate lung tissue, surfaces or vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dislocation lever
Risk classification:	Ir
Basic-UDI-DI:	405018300000290XG
Intended purpose:	Dislocation levers are used to remove the humeral head.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nose wing hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000366XQ
Intended purpose:	Nose wing hook are used to grasp and retract nostrils.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nerve root hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000219XA 405018300000344XE 405018300000521XC
Intended purpose:	Nerve root hooks are used to grip and retract nerve roots / nerves.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Progenitors / chin holders
Risk classification:	Ir
Basic-UDI-DI:	405018300000192XF
Intended purpose:	Progenitors / chin holders are used to grip and retract soft tissues of the lower jaw.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Prostate hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000260X7
Intended purpose:	Prostate hooks are used to grip and retract the prostate.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ramus hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000193XH
Intended purpose:	Ramus hooks are used to grasp and retract in front of the descending ramus of the lower jaw.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Mucosal hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000190XB
Intended purpose:	Mucosal hooks are used to enlarge mucosal incisions.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Spatulas
Risk classification:	Ir
Basic-UDI-DI:	405018300000205WX 405018300000329XJ 405018300000534XM
Intended purpose:	Spatulas are used to introduce material into bone cavities, to manipulate tissue, or to remove material from a surface or vessel.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Spina nasalis hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000367XS
Intended purpose:	Spina nasalis hooks are used to grasp and retain periosteal tissue on the spina nasalis.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Pointed hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000376XT
Intended purpose:	Pointed hooks for the middle ear are used to remove foreign bodies from the ear and to fix structures in the ear or exert traction on the tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Split separators

Risk classification:	Ir
Basic-UDI-DI:	405018300000341X8 405018300000524XJ
Intended purpose:	Split separators are used to lengthen bone cuts.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	S-retractors
Risk classification:	Ir
Basic-UDI-DI:	405018300000221WV
Intended purpose:	S-retractors are used to widen the opening to the surgical site in order to remove the gallbladder from the body.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Strabismus hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000194XK
Intended purpose:	Strabismus hooks are used to hold the eye muscle or exert traction on it.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Dilator
Risk classification:	Ir
Basic-UDI-DI:	405018300000532XH
Intended purpose:	Tracheal dilators are used to widen tracheal structures and passages.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Surgical tracheal hooks are used to fix tracheal tissue or to apply traction to the tissue.
Risk classification:	Ir
Basic-UDI-DI:	405018300000202WR
Intended purpose:	Surgical tracheal hooks are used to fix tracheal tissue or to apply traction to the tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vascular dilator
Risk classification:	Ir
Basic-UDI-DI:	405018300000286XR
Intended purpose:	Vascular dilators are used to widen a vessel.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Vein hooks
Risk classification:	Ir
Basic-UDI-DI:	405018300000525XL
Intended purpose:	Vein hooks are used to grasp and retract veins.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Visual dilator
Risk classification:	Ir
Basic-UDI-DI:	405018300000530XD
Intended purpose:	Dilators are used to dilate lumens in the body.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Soft tissue hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000196XP
Intended purpose:	Soft tissue hooks are used to grip, stabilise and retract soft tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Wisdom tooth hook
Risk classification:	Ir
Basic-UDI-DI:	405018300000533XK
Intended purpose:	Wisdom tooth hooks are used to remove impacted wisdom teeth from their alveolar processes.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Retractor
Risk classification:	Ir
Basic-UDI-DI:	405018300000188XQ
Intended purpose:	Retractors are used to separate tissue or other anatomical parts to expose or access organs or tissues.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Biopsy forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000218X8
Intended purpose:	Biopsy forceps for flexible endoscopy are used to remove tissue endoscopically.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Scissors forceps
Risk classification:	Ir
Basic-UDI-DI:	405018300000120WN
Intended purpose:	Scissors forceps are used for the endoscopic cutting of sutures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Handles of polypectomy snares
Risk classification:	Ir
Basic-UDI-DI:	405018300000618XU
Intended purpose:	The HF polypectomy snares are intended for use in endoscopies of the gastrointestinal tract for the removal (ectomy) of colorectal polyps.

(ectomy) of colorectal polyps for therapeutic or diagnostic purposes for histological examination in
in conjunction with an endoscope using high-frequency current.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	Polypectomy snares
Risk classification:	IIb
Basic-UDI-DI:	405018300000617XS
Intended purpose:	The HF polypectomy snares are intended for use in endoscopies of the gastrointestinal tract to remove (ectomize) (ectomy) of colorectal polyps for therapeutic or diagnostic purposes for histological examination in used in conjunction with an endoscope by means of highfreuency current

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	ADSON suction tubes
Risk classification:	IIa
Basic-UDI-DI:	405018300000021WK
Intended purpose:	ADSON tube is used to aspirate deposits, residues, blood, and other fluids from the surgical site to enable a better view of the surgical field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	ANDREWS-PYNCHON Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000015WQ
Intended purpose:	ANDREWS-PYNCHON is used to remove fluid collections, blood and debris from the operating site, in order to view critical structures, such as blood vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	BARON Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000023WP
Intended purpose:	BARON suction tube is used for atraumatic cleaning of the operating field, through which the view of blood vessels and other structures is improved.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	BELLUCCI Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000593Y5

Intended purpose:	The BELLUCCI suction tube serves as a channel for the aspiration of blood, fluids and other tissue residues during a surgical procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	COOLEY Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000591XZ
Intended purpose:	The COOLEY suction tube is used to improve visibility of the surgical field by aspirating liquids, debris and particles.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	DE BAKEY Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000016WS
Intended purpose:	DE BAKEY suction tube severs as a conductor for the suction of blood, fluids and other tissue residues during a surgical procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	FERGUSSON (POPPEN) Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000019WY
Intended purpose:	FERGUSSON (POPPEN) suction tube is used for the atraumatic suction of liquids from cavities, especially during otological surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	FRAZIER Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000017WU
Intended purpose:	FRAZIER suction tube is used to atraumatically clean the surgical site and to expose vital structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	FUKUSHIMA Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000022WM
Intended purpose:	FUKUSHIMA suction tube is a flexible suction tube that is used to aspirate liquids from areas that are difficult to access.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	GUILLEN suction raspatorium

Risk classification:	IIa
Basic-UDI-DI:	405018300000594Y7
Intended purpose:	The GUILLEN suction raspatory is used to scrape tissue and aspirate fluids during a rhinological procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	MAGILL Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000592Y3
Intended purpose:	The MAGILL suction tube is used to aspirate blood and other fluids, as well as small tissue fragments from the surgical area.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	PLESTER Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000018WW
Intended purpose:	PLESTER suction tube is used to remove liquids, debris of foreign bodies from the nasal cavity, maxillary antrum, or other small anatomical cavities.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	POOLE Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000590XX
Intended purpose:	The POOLE suction tube is used to suck out large accumulations of liquid from cavities.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	SCHUKNECHT Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000024WR
Intended purpose:	SCHUKNECHT suction tube is used for atraumatic cleaning of the operating field, through which the view of blood vessels and other strictures is improved.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Van Eicken sinus irrigation tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000154X7

Intended purpose:	VAN EICKEN frontal sinus irrigation tube is used to irrigate the surgical field, clean infected tissue, and prevent it from spreading.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	WALTON-YANKAUER Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000588YC
Intended purpose:	The WALTON-YANKAUER suction tube is used to reject fluids and debris to clear the view of the surgical site.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	YANKAUER Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000008WT
Intended purpose:	YANKAUER suction tube is used to remove fluids and residues, thus clearing the surgical site.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	YASARGIL Suction tube
Risk classification:	IIa
Basic-UDI-DI:	405018300000020WH
Intended purpose:	YASARGIL suction tube is used to aspirate debris and liquids and thus enable an improved view of the operating field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Heparin suction cannula with button
Risk classification:	IIa
Basic-UDI-DI:	405018300000152X3
Intended purpose:	The heparin irrigation cannulas are used to inject solution into vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Infusion cannula
Risk classification:	IIa
Basic-UDI-DI:	405018300000153X5

Intended purpose:	The infusion cannula is used to create an atraumatic access to the venous system and to inject and remove fluids from there.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	MOCK heparin needle with button
Risk classification:	IIa
Basic-UDI-DI:	405018300000151WZ
Intended purpose:	The MOCK Heparin needles are used to probe small blood vessels or inject solutions via an atraumatic access.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	NOVAK suction curette
Risk classification:	IIa
Basic-UDI-DI:	405018300000230WW
Intended purpose:	The NOVAK suction curette is used to scrape tissue from the uterus and to aspirate fluids..

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	RANDALL suction curette
Risk classification:	IIa
Basic-UDI-DI:	405018300000230WW
Intended purpose:	The RANDALL suction curette is used to grasp the uterine wall and scrape away some of the tissue of the uterine cavity.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	MiniFESS Straight Suction
Risk classification:	IIa
Basic-UDI-DI:	405018300000155X9
Intended purpose:	The suction / irrigation cannulas are intended for aspiration of liquids and fragments. They are also intended for irrigation with liquids. The suction / irrigation cannulas can be used together with navigation systems to better navigate the instrument in the human body during application.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Suction/irrigation systems

Risk classification:	IIa
Basic-UDI-DI:	405018300000355XK
Intended purpose:	The suction/ irrigation systems for laparoscopy are used to rinse the operating area and/ or to suck off the liquids and tissue fragments that have accumulated during the procedure.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	SCHMID cannula
Risk classification:	IIa
Basic-UDI-DI:	405018300000150WX
Intended purpose:	The SCHMID irrigation cannulas are used to inject solution into vessels.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	VERES insufflation cannula
Risk classification:	IIa
Basic-UDI-DI:	405018300000076XC
Intended purpose:	A VERES Insufflation Cannula is used to insufflate carbon dioxide through an atraumatic access to the peritoneal cavity and thus to generate a pneumoperitoneum.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	LANDAU Trocar
Risk classification:	IIa
Basic-UDI-DI:	405018300000595Y9
Intended purpose:	LANDAU trocars are used to provide access to a body cavity and to aspirate fluids via the tube or to irrigate the surgical site via an irrigation tube.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Puncture cannula Needle
Risk classification:	IIa
Basic-UDI-DI:	405018300000356XM
Intended purpose:	Puncture needles are used to puncture tissues and organs, to inject fluids or a contrast medium, or to aspirate fluids.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	OLSEN SWAN cholangiography forceps
Risk classification:	IIa

Basic-UDI-DI:	405018300000573XX
Intended purpose:	Cholangiography forceps are intended to be used to grasp the bile ducts and to place a contrast catheter for intraoperative visualization of the gallbladder or bile ducts.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Cystoscopes
Risk classification:	IIa
Basic-UDI-DI:	405018300000580XU
Intended purpose:	Cystoscopes are intended for endoscopic visualization of inner anatomical structures in the area of the urethra and urinary bladder.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Hysteroscopes
Risk classification:	IIa
Basic-UDI-DI:	405018300000581XW
Intended purpose:	Hysteroscopes are designed for endoscopic visualization of inner anatomical structures in the uterine region.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Nephroscopes
Risk classification:	IIa
Basic-UDI-DI:	405018300000582XY
Intended purpose:	Nephroscopes are designed for endoscopic visualization of inner anatomical structures in the area of the kidney.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ureterorenoscopes
Risk classification:	IIa
Basic-UDI-DI:	405018300000583Y2
Intended purpose:	Ureterorenoscopes are intended for endoscopic visualization of inner anatomical structures in the area of the ureters and renal pelvises.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Arthroscopes
Risk classification:	IIa
Basic-UDI-DI:	405018300000584Y4
Intended purpose:	Rigid arthroscopes are designed for endoscopic visualization of inner anatomical structures in joints and skeletal structures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005520
Certificate ID: 1000220878

Product name:	Laparoscopes
Risk classification:	IIa
Basic-UDI-DI:	405018300000585Y6
Intended purpose:	Laparoscopes are intended for endoscopic visualization of inner anatomical structures in the area of the abdominal cavity and the organs located therein.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	HF- electrodes
Risk classification:	IIb
Basic-UDI-DI:	405018300000586Y8
Intended purpose:	HF electrodes are intended for endoscopically controlled tissue resection, vaporization, enucleation, incision or coagulation in urology and gynecology.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Electrode holder
Risk classification:	IIa
Basic-UDI-DI:	405018300000587YA
Intended purpose:	Electrode holders, HF surgery are used to hold and fix the endoscope as well as for endoscopically controlled insertion of the electrode (cold electrode, HF electrode, stricture gauge) or the laser probe into the surgical site.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Sheats
Risk classification:	IIa
Basic-UDI-DI:	405018300000601XB
Intended purpose:	Sheaths are used to create a working or irrigation channel during surgical procedures for diagnosis and therapy in urology and gynecology

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	inserts
Risk classification:	IIa
Basic-UDI-DI:	405018300000602XD
Intended purpose:	Working inserts enable the introduction of working instruments into the surgical field via the integrated working channel. They are used in conjunction with sheaths and endoscopes during surgical procedures for diagnosis and therapy in urology and gynecol.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	optical bridges
Risk classification:	IIa

Basic-UDI-DI:	405018300000603XF
Intended purpose:	Optical bridges enable visualization as well as the insertion of instruments into the surgical field. They are used in conjunction with sheaths and endoscopes in surgical procedures for diagnosis and therapy in urology and gynecology.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	Endoor Cut scissor inserts
Risk classification:	IIb
Basic-UDI-DI:	405018300000574XZ
Intended purpose:	The Endoor Cut disposable scissor inserts are used in conjunction with a reusable handle and shaft for cutting while simultaneously coagulating soft tissue sections, organs or foreign bodies via natural or surgically created accesses.

Device category:	**MDA 0312 - Other active non-implantable surgical devices**
Product name:	Endoor C coagulation forceps
Risk classification:	IIb
Basic-UDI-DI:	405018300000575Y3, 405018300000576Y5, 405018300000578Y9, 405018300000579YB, 405018300000577Y7
Intended purpose:	The dismountable, monopolar Endoor C coagulation forceps are used for endoscopically controlled grasping, manipulation and cutting during simultaneous coagulation, as well as for dissection and sampling of soft tissue sections, organs or foreign bodies via naturally or surgically created accesses.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Rib spreader
Risk classification:	IIa
Basic-UDI-DI:	405018300000596YB
Intended purpose:	The Rib spreader is used to spread the ribs during a thoracotomy to provide better access to the surgical field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Ring retractor system
Risk classification:	IIa
Basic-UDI-DI:	405018300000597YD
Intended purpose:	The Ring Retractor System is used to fix the abdominal cavity, organs, skin as well as internal tissues to provide better access to the surgical field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	GELPI Retractor

Risk classification:	IIa
Basic-UDI-DI:	405018300000598YF
Intended purpose:	The GELPI retractor is used to retract thick and hard tissue to provide better access to the surgical field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Abdominal Retractor
Risk classification:	IIa
Basic-UDI-DI:	405018300000600X9, 405018300000606XM,405018300000607XP, 405018300000608XR
Intended purpose:	The Abdominal Retractor is used to hold tissues and organs in place to provide better access to the surgical field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	CHARNLEY retractor
Risk classification:	IIa
Basic-UDI-DI:	405018300000604XH
Intended purpose:	The CHARNLEY retractor is used to fix tendons and skin for better access to the surgical field. The weight system is used to pull apart hard fibrous tissue.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	retractors
Risk classification:	IIa
Basic-UDI-DI:	405018300000609XT, 405018300000611XE, 405018300000612XG, 405018300000613XJ, 405018300000614XL, 405018300000619XW, 405018300000620XF, 405018300000621XH, 405018300000622XK, 405018300000623XM, 405018300000624XP
Intended purpose:	The retractor is used to retract incision surfaces and wounds to provide better access to the surgical field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	LEYLA retractor
Risk classification:	IIa
Basic-UDI-DI:	405018300000616XQ
Intended purpose:	Retractors / holding systems with adjustable angle enable hands-free use of additional instruments during an operation. They can be designed rigidly or individually adaptable, such as spreader with rail (rigid), Leyla retractor system (flexible).

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005520
Certificate ID: 1000220878

Examinations and tests performed:
448891_A209802MED_02 dated 10.07.2022
448891_A212926MED_03 polypectomy snares dated 2024-12-09
448891_A212926MED_04 Suction/irrigation instrument dated 2025-01-27

Further conditions for or limitations to the validity of the certificate:
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-12-15	170779053	Addition of Product “polypectomy snares TF16”
02	2025-01-26	1000209540	Addition of Product “Suction/irrigation instruments TF12”
03	2025-01-31	1000214224	Addition of product files using the “TF-02, TF-04, TF-07, TF-10 and TF11” sampling procedure