

Das Unternehmen

The company

ASANUS Medizintechnik GmbH
take off Gewerbepark 2
78579 Neuhausen ob Eck
Germany (Kreis Tuttlingen)
SRN: DE-MF-000005540

erklärt hiermit in alleiniger Verantwortung und unter Anwendung des Artikels 120 der Verordnung (EU) 2017/745, dass folgende Medizinprodukte (siehe Anhang zu dieser Konformitätserklärung)

Bezeichnung: Kraftausübende Instrumente Stopfer, Hämmer, Schraubendreher etc.

Basic-UDI-DI: siehe Artikelliste im Anhang

Risikoklasse: IR

Regel - Spiegelstrich: siehe Artikelliste im Anhang

Zweckbestimmung: siehe Annex I zu dieser Erklärung

die Anforderungen des Anhang IX Kapitel I und III der MDR 2017/745 erfüllen.

Das Konformitätsbewertungsverfahren wird derzeit in Zusammenarbeit mit der Benannten Stelle DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main, Kennnummer 0297 durchgeführt.

Die Produkte sind somit zur Anbringung des CE-Zeichens zugelassen.

Angewandte harmonisierte Normen, nationale Vorschriften oder andere normative Dokumente:

- Verordnung (EU) 2017/745 (MDR)
- DIN EN ISO 13485:2021
- Medizinproduktegesetz - MPG

Diese Erklärung besitzt eine Gültigkeit bis einschließlich 2028-12-31

hereby declares under sole responsibility and under application of Article 120 of regulation (EU) 2017/745, that the following medical devices (see appendix to this declaration of conformity)

Description: Force-exerting instruments tampers, mallets, screwdrivers etc.

Basic-UDI-DI: see attached product list

Risk-class: IR

Rule - Dash: see attached product list

Intended purpose: see Annex I to this declaration

meet the requirements of Annex IX chapter I and III of the mdr 2017/745.

The conformity assessment procedure is currently being carried out in collaboration with the notified body DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main, identification number 0297.

The products are therefore approved for applying the CE mark.

Applied harmonised standards, national regulations or other normative documents:

- Verordnung (EU) 2017/745 (MDR)
- DIN EN ISO 13485:2021
- Medizinproduktegesetz - MPG (national law)

This declaration is valid until including 2028-12-31



Datum / date: 2024-05-27


Unterschrift / signature

Zugeordnete Artikel: / related products:

Product groups	EMDN-Nr	EMDN NAME	Basic UDI-DI	Risk	Rule
\$PA-ABRAS12B	Z12130503	ORTHOPAEDIC SURGICAL DRILLS	4060414PA-ABRAS12B3Z	IR	6 - 2
\$PA-ACC11	REF	Name	UDI/GTIN		
	L0903	ORTHOPEDIC SURGERY HAMMERS, REUSABLE	4060414PA-ACC1136	IR	6 - 2
	REF	Name	UDI/GTIN		
	KN2000F	NOVOTEX ferrozell mallet 250mm 10" head Ø42mm small version of KN2010	04060414241501		
	KN2010F	NOVOTEX ferrozell mallet 270mm 10 3/4" head Ø48mm	04060414241518		
	KN2020F	Ferrozell mallet 265mm 10 1/2" head Ø50mm	04060414241525		
	KN2039	Mini mallet 165mm 6 1/2" head Ø20mm lead filled extra heavy 80g	04060414096484		

KN2040	MEAD mallet 190mm 7 1/2" 180gr head Ø20mm with interchangeable plastic inserts	04060414096491
KN2045	PARTSCH mallet 180mm 7 1/8" 200gr head Ø22mm	04060414096507
KN2049	Mallet 185mm 7 1/4" 140gr head Ø25mm	04060414096514
KN2050	Mallet 185mm 7 1/4" 135gr head Ø25mm with interchangeable plastic inserts	04060414096521
KN2070	COTTLE mallet 185mm 7 1/4" 235gr head Ø30mm flat - convex	04060414096545
KN2075	LUCAE mallet 185mm 7 1/4" 130gr head Ø25mm flat - cross serrated	04060414096552
KN2078	Mallet 190mm 7 1/2" 155gr head Ø24.5mm flat - serrated	04060414096569
KN2080	HAJEK mallet 220mm 8 3/4" 140gr head Ø27mm	04060414096583
KN2090	Mallet 245mm 9 3/4" 350gr head Ø30mm with PPSU handle with interchangeable plastic inserts	04060414096590
KN2105	Mallet 180mm 7 1/8" head Ø25mm lead filled	04060414096613
KN2109	Mallet 185mm 7 1/4" 520gr head Ø19mm	04060414096637
KN2110	BERGMANN mallet 235mm 9 1/4" 245gr head Ø30mm	04060414096644
KN2120	Mallet 245mm 9 3/4" 400gr head Ø28mm + Ø42mm	04060414096651
KN2121	Mallet 240mm 9 1/2" 720gr head Ø30mm + Ø42mm stainless steel	04060414096668
KN2125	COLLIN mallet 200mm 8" 220gr head Ø30mm stainless steel	04060414096675
KN2130	BERGMANN mallet 245mm 9 3/4" 500gr head Ø45mm	04060414096682
KN2140	WAGNER mallet 235mm 9 1/4" head Ø35mm with interchangeable plastic inserts	04060414096699
KN2170-1	OMBREDANNE mallet 240mm 9 1/2" 1010gr head Ø40mm with steel handle	04060414096743
KN2180	HEATH mallet 185mm 7 1/4" 700gr head Ø40mm	04060414096750

KN2181	HEATH mallet 190mm 7 1/2" 1000gr head Ø45mm	04060414096767
KN2190	Mallet 230mm 9 1/8" 425gr head Ø13.5mm + Ø27.0mm	04060414096781
KN2191	Mallet with exchangeable disks 245mm 9 3/4" steel head Ø30mm 215g with PPSU handle	04060414096798
OR2660	HEERMANN metal mallet 195mm 7 3/4" with holow handle	04060414156225
L0999	ORTHOPEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE - OTHER	4060414PA-ACC
REF	Name	UDI/GTIN
KN0113	Slotted hammer extractor 295mm 11 3/4" with PPSU handle	04060414091038
KN0198	ZIELKE tamper 165mm 10x6mm serrated tip pitch 1.0mm	04060414091106
KN2192	Impactor-Extractor 350mm 14" straight jaw 15x10mm checked metal with PPSU handle	04060414096804
KN2193	Impactor-Extractor 280mm 11 1/8" straight jaw15x6mm checked metal with PPSU handle	04060414096811
KN2194	Impactor-Extractor 280mm 11 1/8" curved jaw 15x6mm checked metal with PPSU handle	04060414096828
KN2195	Impactor-Extractor 280mm 11 1/8" straight jaw 17x6.5mm metal with PPSU handle	04060414096835
KN2196	Impactor-Extractor 275mm 11" straight jaw 17x7.0mm metal with PPSU handle	04060414096842
KN2197	Impactor-Extractor 305mm 12 1/8" width 10.2mm metal with PPSU handle	04060414096859
KN2198	Impactor-Extractor 275mm 11" Ø7.0mm metal	04060414096866
KN2200	Tamper 200mm 8" Ø12mm with PPSU handle	04060414096873
KN2200S	Tamper 200mm 8" Ø12mm with metal handle	04060414229936
KN2210	Tamper 200mm 8" Ø14mm with PPSU handle	04060414096880
KN2210S	Tamper 200mm 8" Ø14mm with metal handle	04060414229929
KN2220	Tamper 200mm 8" Ø16mm	04060414096897

	with PPSU handle	
KN2220S	Tamper 200mm 8" Ø16mm with metal handle	04060414229974
KN2229	Tamper for bone material 160mm 6 1/4" Ø2.0mm	04060414096903
KN2230	Tamper for bone material 160mm 6 1/4" Ø3.0mm	04060414096910
KN2231	Tamper for bone material 160mm 6 1/4" Ø4.0mm	04060414096927
KN2232	Tamper for bone material 160mm 6 1/4" Ø5.0mm	04060414096934
KN2233	Tamper for bone material 160mm 6 1/4" Ø6.0mm	04060414096941
KN2234	Tamper for bone material 6 1/4" 160mm Ø8.0mm	04060414096958
KN2235	Tamper for bone material 6 1/4" 160mm Ø9.0mm	04060414096965
KN2236	Tamper for bone material 6 1/4" 160mm Ø10.0mm	04060414096972
KN2243	Tamper for bone material 200mm 8" Ø6.0mm	04060414096989
KN2250	Tamper for bone material 6 1/4" 160mm Ø7.0mm	04060414096996
KN2264	SALZBURGER nail impactor 4mm for round curved nails	04060414097009
KN2265	SALZBURGER nail impactor 5mm for round curved nails	04060414097016
KN2268	SALZBURGER nail impactor 8mm for round curved nails	04060414097023
KN2270	PASSOW hemostasis chisel 120mm 4 3/4" 2.5x2.5mm	04060414097030
KN2276	Micro offset central canal impactor 180mm 7 /18" central	04060414097047
KN2277	Micro lateral gutter Impactor 180mm 7 1/8" tamper 8x4mm	04060414097054
KN2280	PASSOW hemostasis chisel 120mm 4 3/4" 3.5x3.5mm	04060414097061
KN2285	Offset central canal impactor 220mm 8 3/4" tamper 10x5mm	04060414097078
KN2286	Offset central canal impactor 220mm 8 3/4" tamper 13x7mm 30°	04060414097085
KN2290	HAASE tamper 100mm 4" for interlocking-OP	04060414097092

KN2293	SYPERT tamper 290mm 11 1/2" 3x8mm with PPSU handle	04060414097108
KN2294	SYPERT tamper 290mm 11 1/2" 4x10mm with PPSU handle	04060414097115
KN2295	SYPERT tamper 290mm 11 1/2" 5x15mm with PPSU handle	04060414097122
KN2296	SYPERT tamper 290mm 11 1/2" 6x20mm with PPSU handle 290 mm, 11 1/2" total length	04060414097139
KN5095	Impactor for hip joint prosthesis 260mm 10 1/4" with Polyamid head	04060414103991
KN6515	FOERSTNER plunger with notch	04060414105407
KN6526	ROTO rod bender 285mm 11 1/4" for rods Ø7.0mm measurement set up	04060414105476
KN6532	SURE QUICK removal hammer 350mm 14" 440g for wires and nails for pliers KN6599-6601 and KN6546-6548	04060414105506
KN6533	SURE QUICK removal hammer 400mm 16" 700g for wires and nails for pliers KN6599-6601 and KN6546-6548	04060414105513
KN6605	Bending iron 120mm 4 3/4" for boring wires up to Ø2.7mm	04060414105889
KN6630	WAGNER wire bending iron 300mm 12" up to Ø3.0mm	04060414105957
MN0011	CASPAR tamper 200mm 8" Ø3.5mm with PPSU handle	04060414110395
MN0011S	CASPAR tamper 200mm 8" Ø3.5mm with steel handle	04060414229950
MN0012	CASPAR tamper 200mm 8" Ø5.0mm with PPSU handle	04060414110401
MN0012S	CASPAR tamper 200mm 8" Ø5.0mm with steel handle	04060414229943
MN0013	CASPAR tamper 200mm 8" Ø8.0mm with PPSU handle	04060414110418
MN0013S	CASPAR tamper 200mm 8" Ø8.0mm with steel handle	04060414229967
WS0450	Bone impact instrument 222mm 8 3/4" double ended Ø11mm + Ø14mm	04060414216875

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\$PA-ACC14	L150799	ORTHODONTIC INSTRUMENTS, REUSABLE-OTHER	4060414PA-ACC143C	IR	6 - 2
	REF	Name	UDI/GTIN		
	DN0100	LUNIATSCHEK gauze packer 190mm 7 1/2"	04060414015904		
	DN0180	ELLIOT amalgam plugger double-ended	04060414015935		
	DN0183	HAUBEIL amalgam plugger double-ended figure 1+2	04060414015942		
	DN0202	SEIDEL scaler 150mm 6" sharp with hatches	04060414015959		
	DN0400	Fill instrument for dental ambit figure 0	04060414016024		
	DN0401	Fill instrument for dental ambit figure 1	04060414016031		
	DN0404	Fill instrument for dental ambit figure 4	04060414016048		
	DN0502	Instrument for plastic filling 1.2mm+1.6mm figure 2	04060414016062		
	DN0503	Instrument for plastic filling 2.0mm+2.5mm figure 3	04060414016079		
	DN0504	Instrument for plastic filling 2.8mm+3.2mm figure 4	04060414016086		
	DN0537	Instrument for plastic filling figure 37	04060414016093		
\$PA-ACC27	L26	SURGICAL SCREWDRIVERS, REUSABLE	4060414PA-ACC273M	IR	6 - 2
	REF	Name	UDI/GTIN		
	KN0001	Screwdriver for bone surgery 170mm 6 3/4" single slot	04060414090765		
	KN0002	Screwdriver for bone surgery 250mm 10" Phillips	04060414090772		
	KN0003	Screwdriver for bone surgery 250mm 10" Phillips	04060414090789		
	KN0004	Screwdriver	04060414090796		
	KN2140-1	Wrench for WAGNER mallet KN2140	04060414096705		
	KN3531	Allen key for chisel handle KN3530 Key width 3mm	04060414101201		
	KN3532	Allen key width 3,5mm	04060414548426		
	KN4701	Screwdriver hexagonal teflon handle	04060414102888		
	KN4703	Screwdrivers mall with holding sleeve	04060414102901		
	KN4704	Screwdrivers mall with holding sleeve	04060414102918		

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KN5881	Wrench for hand drill KN5880	04060414104790
KN5901	Wrench for hand drill KN5900	04060414104813
KN8001	Screwdriver for small screws 250mm 10" hexagonal 2.5mm	04060414106770
KN8002	Screwdriver for small screws 245mm 9 3/4" hexagonal 3.5mm	04060414106787
KN8003	Screwdriver for large screws 220mm hexagonal 3.5mm	04060414106794
MN2280	Allen Wrench hexagonal for approximator	04060414116090
WH7071-1	CASPAR screwdriver for retractor WH7070	04060414213256
WS0008	CASPAR screw driver for distraction screws WS0020 WS0021 WS0028	04060414215571
WS0045	CASPAR bone splinter container	04060414215793
\$PA-CUT23	L090999 ORTHOPEDIC SURGERY SHARP INSTRUMENTS, REUSABLE - OTHER	4060414PA-CUT23AN
REF	Name	UDI/GTIN
DZ0502	YOUNG loop bending pliers 140mm 5 1/2" for hard spring wire up to Ø0.7mm for labial bow and orthodontics	04060414018165
EKN6525	Power TC wire cutter wire: soft up to 3,0 mm, hard 2,2 mm 220 mm, 8 3/4" total length	04060414433074
EKN6545	DALIA Power TC wire cutter str, wire: soft up to 3,0 mm, hard 2,2mm 235 mm, 9 1/4" total length	04060414433081
EKN6550	DALIA Power TC wire cutting pliers ang, wire: soft up to 3,0 mm, hard 2,5mm 230 mm, 9 1/8" total length	04060414433098
EKN6555	DALIA POWER-TC front and lateral cutter 180mm 7 1/8" for wire soft up to Ø1.6mm	04060414022971
EKN6560	DALIA POWER-TC wire cutter 180mm 7 1/8" curved for wire soft up to Ø2.0mm hard Ø1.7mm	04060414338607
EKN6566	DALIA "Easy Cutter" TC wire cutter wire until Ø 2-3,5 mm, Platten until 2mm 240 mm, 9 1/2" total length	04060414433104
KN6514	EASY-CUT pin cutter 570mm 22" for hard pins up to Ø6.35mm special tempered steel	04060414105391
KN6518	Wire cutter 260mm 10 1/4" for hard wire up to Ø3.2mm special tempered steel	04060414105414

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KN6519	Wire cutter 380mm 15 1/8" for hard wire up to Ø4.7mm special tempered steel	04060414105421
KN6520	POWER TC wire cutter 145mm 5 3/4" for hard wire up to Ø1.5mm and soft wire up to Ø2.0mm	04060414105438
KN6521	Wire cutting plier with TC blades 180mm 7 1/8"	04060414105445
KN6524	Wire cutter 160mm 6 1/4" for hard wire up to Ø2.0mm and soft wire up to Ø2.2mm	04060414105452
KN6525	POWER TC wire cutter 220mm 8 3/4" for hard wire up to Ø2.2mm and soft wir up to 3.0mm	04060414105469
KN6530	Microplate circular cutting pliers 110mm 4 1/4"	04060414105490
KN6535	Microplate cutting pliers 110mm 4 1/4"	04060414105520
KN6540	Microplate cutting pliers 110mm 4 1/4"	04060414105544
KN6541	Wire cutter 145mm 5 3/4" straight for wire soft up to Ø1.5mm hard Ø1.0mm	04060414105551
KN6542	POWER-TC wire cutter 140mm 5 1/2" angled for wire soft up to Ø1.6mm hard Ø1.0mm	04060414105568
KN6545	POWER-TC wire cutter 235mm 9 1/4" straight for wire soft up to Ø3.0mm hard Ø2.2mm	04060414105575
KN6550	HARVEY POWER-TC wire cutter 230mm 9 1/8" angled for wire soft up to Ø3.0mm hard Ø2.5mm	04060414105612
KN6550T	POWER-TC wire cutter 235mm 9 1/8" upwards angled articulated titanium	04060414105629
KN6555	POWER-TC front and lateral cutter 180mm 7 1/8" for wire soft up to Ø1.6mm	04060414105636
KN6560	POWER-TC wire cutter 180mm 7 1/8" curved for wire soft up to Ø2.0mm hard Ø1.7mm	04060414105650
KN6560-1	POWER-TC wire cutter 180mm 7 1/8" curved small angle	04060414105667
KN6560T	POWER-TC wire cutter 180mm 7 1/8" curved for wire soft up to Ø2.0mm hard Ø1.7mm TITANIT	04060414105674
KN6562	KIRSCHNER wire cutter 160mm 6 1/4"	04060414105681

KN6565	POWER-TC side cutter 240mm 9 1/2"	04060414105704
KN6566	EASY CUTTER POWER-TC wire cutter 240mm for wire from Ø2 to Ø3.5mm and plates up to 2mm	04060414105711
KN6567	Front action wire cutter 185mm 7 1/8" for wire soft up to Ø2.4mm hard Ø1.6mm cannulated Ø2.5mm	04060414105728
KN6568	Wire cutter 165mm 6 1/2" straight for wire soft up to Ø3.5mm hard Ø2.5mm	04060414105735
KN6570	Bolt cutter 470mm 18 3/4" for wires screws and nails up to Ø6mm	04060414105759
KN6575	Bolt cutter 320mm 12 3/4" for wires screws and nails up to Ø6mm	04060414105766
MF0880	NIEDERDELLMANN wire ligature splint	04060414110104
MF0890	OBWEGESER wire ligature forceps 137mm 5 1/2"	04060414110111
SC2009	GUILFORD-WRIGHT fine wire scissors 110mm 4 1/4" straight	04060414171952
L0902	ORTHOPEDIC SURGERY LEVERS, REUSABLE	4060414PA-HOO
REF	Name	UDI/GTIN
EKN0440	DALIA LANE-TRETHOWAN bone lever 215mm 8 1/2"	04060414338577
KN0300	Elevator 155mm 6 1/4" width 5.5mm	04060414091113
KN0310	Bone lever 140mm 5 1/2" width 2.8mm	04060414091120
KN0320	Bone lever 150mm 6" width 5.0mm	04060414091137
KN0330	Bone lever 150mm 6" width 7.0mm	04060414091144
KN0338	Bone lever 160mm 6 1/4" backwards curved width 7.0mm	04060414091151
KN0340	BUCK-GRAMKO bone lever 150mm 6" tip width 2.0mm	04060414091168
KN0350	Bone lever 160mm 6 1/4" width 6.0mm	04060414091175
KN0360	Bone lever 160mm 6 1/4" width 8.0mm	04060414091182
KN0370	Bone lever 120mm 4 3/4" width 15x2mm	04060414091229
KN0380	WILLIGER elevator 170mm 6 3/4" width 5.0mm	04060414091236

KN0381	YANKAUER septum elevator 180mm 7 1/8"	04060414091243
KN0385	MAAS.Gen.Hosp. Elevator 160mm 6 1/4" width 6.2mm	04060414091250
KN0386	QUERVAIN elevator 210mm 6 3/4" width 6.0mm with sure-hold handle	04060414091267
KN0387	QUERVAIN elevator 210mm 6 3/4" width 7.0mm with sure-hold handle	04060414091274
KN0388	QUERVAIN elevator 210mm 6 3/4" width 10.0mm with sure-hold handle	04060414091281
KN0390	WILLIGER elevator 170mm 6 3/4" width 5.5mm	04060414091298
KN0391	WILLIGER elevator 170mm 6 3/4" width 7.0mm	04060414091304
KN0398	SEBILEAU elevator 175mm 7" width 3.0mm	04060414091311
KN0400	SEBILEAU elevator 175mm 7" width 5.0mm	04060414091328
KN0405	SEBILEAU elevator 175mm 7" width 17.5mm	04060414091335
KN0410	LANGENBECK elevator 200mm 8" width 8.0mm	04060414091342
KN0420	LANGENBECK elevator 195mm 7 3/4" width 10.0mm	04060414091359
KN0430	QUERVAIN elevator 195mm 7 3/4" width 6.0mm	04060414091366
KN0440	LANE-TRETHOWAN bone lever 215mm 8 1/2"	04060414091373
KN0460	LANGENBECK elevator 230mm 9 1/8" width 11.0mm	04060414091380
KN0470	BRISTOW bone lever 230mm 9 1/8" width 10.5mm	04060414091397
KN0472	CAIRNS elevator 175mm 7" width 9.0mm	04060414091403
KN0480	WAGNER elevator 330mm 13" width 9.0mm	04060414091410
KN0490	TAEGER bone lever 175mm 7" width 12.0mm	04060414091427
KN0500	LANGE-HOHMANN bone lever 250mm 10" width 22.5mm	04060414091441
KN0510	LANGE-HOHMANN bone lever 265mm 10 1/2" width 30.0mm	04060414091458

	with modiefied handle	
KN0520	LANGE-HOHMANN bone lever 280mm 11 1/8" width 33.0mm with modiefied handle	04060414091465
KN0530	HOHMANN bone lever 240mm 9 1/2" width 17.0mm	04060414091472
KN0530-1	HOHMANN bone lever 240mm 9 1/2" width 18.0mm	04060414091489
KN0531	HOHMANN bone lever 240mm 9 1/2" width 18.0mm 2 holes long narrow tip	04060414091496
KN0532	LANGE-HOHMANN bone lever 225mm 9" width 18.0mm 1 hole long narrow tip	04060414091502
KN0533	HOHMANN-ALDINGER bone lever 280mm 11" strongly curved width 24mm 2 hole handle angled	04060414427776
KN0540	WAGNER bone lever 220mm 8 3/4" width 8.0mm	04060414091519
KN0541	WAGNER bone lever 220mm 8 3/4" width 17.0mm	04060414091526
KN0542	HOHMANN bone lever 260mm 10 1/4" width 25.0mm	04060414091533
KN0570	Bone lever 220mm 8 3/4" width 10.0mm	04060414091540
KN0580	Bone lever 240mm 9 1/2" width 17.0mm	04060414091557
KN0585	HOHMANN bone lever 240mm 9 1/2" width 43.0mm sharp	04060414091564
KN0585-1	HOHMANN bone lever 240mm 9 1/2" width 43.0mm blunt stronly curved hollow	04060414091571
KN0590	HOHMANN bone lever 260mm 10 1/4" width 24.0mm	04060414091588
KN0600	HOHMANN bone lever 285mm 11 1/4" width 13/35mm	04060414091595
KN0601	"HOHMANN" bone lever 40mm blade 290mm 11 1/2" total legth	04060414341300
KN0610	VERBRUGGE-MUELLER bone lever 240mm 9 1/2" width 44.0mm	04060414091601
KN0620	HOHMANN bone lever 250mm 10" blade width 24.0mm	04060414091618
KN0630	HOHMANN bone lever 260mm 10 1/4" width 25.0mm	04060414091625

KN0640	SCHUMACHER bone lever 290mm 11 1/2" width 18/35mm	04060414091649
KN0649	BENETT bone lever 235mm 9 1/4" width 45.0mm	04060414091656
KN0650	BENETT bone lever 235mm 9 1/4" width 65.0mm	04060414091663
KN0660	MURPHY-LANE luxation hook 300mm 12" double-ended	04060414091670
KN0730	ADSON elevator 170mm 6 3/4" curved blunt width 7.0mm	04060414091908
KN0783	McGLAMY metatarsal elevator 165mm 6 1/2" sharp width 13.0mm	04060414092004
KN0785	McGLAMY metatarsal elevator 165mm 6 1/2" sharp width 15.0mm	04060414092011
KN0787	McGLAMY metatarsal elevator 165mm 6 1/2" sharp width 17.0mm	04060414092028
KN6960	MAGNUM-COBB elevator 340mm 13 1/2" extra long width 9.0mm with PPSU handle	04060414106718
KN6961	MAGNUM-COBB elevator 340mm 13 1/2" extra long width 15.0mm with PPSU handle	04060414106725
KN6962	MAGNUM-COBB elevator 340mm 13 1/2" extra long width 20.0mm with PPSU handle	04060414106732
KN6963	MAGNUM-COBB elevator 340mm 13 1/2" extra long width 25.0mm with PPSU handle	04060414106749
KN6964	MAGNUM-COBB elevator 340mm 13 1/2" extra long width 30.0mm with PPSU handle	04060414106756
KN6965	MAGNUM-COBB elevator 340mm 13 1/2" extra long width 35.0mm with PPSU handle	04060414106763
KN9106	Hanger alone for weight KN9107 and for Femur lever KN9108	04060414106800
KN9107	Weight alone for femur lever KN9108	04060414106817
KN9108	Femur lever alone 330mm 13 1/8" usable with KN9107-1200G and KN9106	04060414106824
KN9109	Femur lever set consisting of KN9106 KN9107-1200G and KN9108	04060414106831
KN9200	Humerus head retractor 190mm 7 1/2" blade 37mm 3mm strong oval fenestrated	04060414106848
KN9205	KUJAT-FUKADA humerus head retractor	04060414106855

190mm 7 1/2" blade 31mm 3mm strong
 oval fenestrated

MF0295 TESSIER bone retractor 180mm 7 1/8" 04060414109030

\$PA-HOOKS11 L149002 ENT LEVERS, REUSABLE 4060414PA-HOOKS113N IR 6 - 2

REF Name UDI/GTIN
 ENS2139 DALIA HOWARTH elevator 220mm 8 3/4"
 double ended sharp-blunt 4.3 + 5.8mm 04060414338676

HA1410 KOENIG elevator 155mm 6 1/8"
 strongly cvurved blunt width 4.5mm 04060414078282

HA1410-1 KOENIG elevator 155mm 6 1/8"
 strongly cvurved sharp 04060414078299

HA1420 KOENIG elevator 150mm 6"
 strongly cvurved 04060414078305

MF0326 DINGMANN zygoma elevator 210mm 8 1/4"
 curved tip 4.6mm 04060414109115

NS2010 COTTLE elevator 200mm 8"
 double ended 3.0 + 2.3mm 04060414149562

NS2020 MASING elevator 220mm 8 3/4"
 double ended graduated 04060414149586

NS2060 FREER elevator 180mm 7 1/8"
 double ended sharp width 4.5 + 4.5mm 04060414149654

NS2070 HALLE elevator 180mm 7 1/8"
 curved blunt width 3.5mm 04060414149661

NS2090 FREER elevator 185mm 7 1/4"
 curved blunt 4,0mm + 6,2mm 04060414149708

NS2091 FREER elevator 180mm 7 1/8"
 double ended sharp width 4.5 + 5.2mm 04060414149722

NS2095 FREER elevator 180mm 7 1/8"
 double ended curved
 1 thick and 1 thin side 04060414149739

NS2096 FREER elevator 185mm 7 1/4"
 double ended curved
 1 thick and 1 thin side 04060414149746

NS2100 FREER elevator 185mm, 7 1/4"
 double ended width 3,6 + 3,7mm
 sharp-blunt 04060414149753

NS2101 FREER elevator 180mm 7 1/8"
 double ended width 4.0 + 4.0mm
 sharp-blunt 04060414149760

NS2102 FREER-JOSEF elevator 200mm 8"
 double ended width 3.3 + 4.5mm
 semi sharp-blunt 04060414149777

NS2103 FREER elevator 185mm 7 1/4"
 double ended width 3.7 + 3.7mm
 sharp-blunt 04060414149784

NS2104	FREER elevator 225mm 9" double ended width 6.0 + 6.0mm sharp-sharp	04060414149791
NS2107	STILLE elevator 240mm 9 1/2" curved with holes	04060414149821
NS2130	KILLIAN elevator 185mm 7 1/4" double ended width 3.4 + 3.5mm sharp-blunt	04060414149869
NS2131	KILLIAN elevator 185mm 7 1/4" double ended blunt-blunt	04060414149876
NS2140	HOWARTH elevator 215mm 8 1/2" double ended width 5.0 + 8.0mm sharp-blunt	04060414149883
NS2142	HILL elevator 225mm 9" double ended width 3.6 + 4.6mm blunt-sharp	04060414149906
NS2150	KILLIAN elevator 185mm 7 1/4" double ended width 4.0 + 5.5mm sharp-blunt	04060414149913
NS2151	KILLIAN elevator 220mm 8 3/4" double ended width 6.3 + 6.3mm sharp-blunt with knurled handle	04060414149920
NS2182	Mc KENTY septum raspatory 145mm 5 3/4" sharp width 5.0mm	04060414149999
NS2970	BOIES nose fracture reconstructor 180mm 7 1/8" oval	04060414151572
NS2980	GOLDMANN nose fracture reconstructor 200mm 7 1/8" round	04060414151589
OR1410	ZAUFAL ear hook 160mm 6 1/4" blunt	04060414154344
OR1420	LUCAE ear hook 140mm 5 1/2" small	04060414154351
OR1430	LUCAE ear hook 140mm 5 1/2" medium	04060414154368
OR1440	LUCAE ear hook 140mm 5 1/2" figure 3	04060414154375
OR1450	ZAUFAL-JANSEN ear hook 150mm 6"	04060414154382
OR1498	ST. BART ear lever 180mm 7 1/8"	04060414154450
OR2280	HUGES stapes elevator 155mm 6 1/2" strongly curved 1.0mm	04060414155709
OR4025	ZOELLNER elevator downwards curved width 2.0mm	04060414157161
OR4026	ZOELLNER elevator upwards curved width 2.0mm	04060414157178

REF	Name	UDI/GTIN
DN0010	PHW papilla elevator 175mm 7" angled, double-ended	04060414015867
DN3080	BEIN root elevator 130mm 5 1/8" for upper roots tip rounded 2mm figure 0	04060414017052
DN3080DD	BEIN root elevator 130mm 5 1/8" for upper roots tip rounded 2mm diamond dusted figure 0	04060414017069
DN3081	BEIN root elevator 130mm 5 1/8" for upper roots tip rounded 3mm figure 1	04060414017076
DN3088	SELDIN root elevator for upper roots rounded figure 3	04060414017113
DN3090	BEIN root elevator 130mm 5 1/8" for upper roots tip rounded 4mm figure 2	04060414017120
DN3120	W.F. BARRY root elevator 110mm 4 1/4" left model with T-handle figure 320L	04060414017182
DN3121	W.F. BARRY root elevator 110mm 4 1/4" left model with T-handle figure 322L	04060414017199
DN3130	W.F. BARRY root elevator 110mm 4 1/4" right model with T-handle figure 320R	04060414017205
DN3131	W.F. BARRY root elevator 110mm 4 1/4" right model with T-handle figure 322R	04060414017212
DN3140	HEIDBRINK root elevator right angled for lower roots	04060414017229
DN3141	HEIDBRINK root elevator left angled for lower roots	04060414017236
DN3142	Root elevator left for lower roots	04060414017243
DN3143	Root elevator right for lower roots	04060414017250
DN3145	BEIN root elevator 140mm 5 1/2" for upper roots tip rounded 5mm	04060414017267
DN3150	FLOR root elevator 130mm 5 1/8" straight for upper roots figure 46	04060414017274
DN3151	SELDIN root elevator 130mm 5 1/8" for upper roots curved tip figure 34	04060414017281
DN3152	SELDIN root elevator 130mm 5 1/8"	04060414017298

	for upper roots right curved tip figure 4R	
DN3153	SELDIN root elevator 130mm 5 1/8" for upper roots left curved tip figure 4L	04060414017304
DN3154	CRYER root elevator 130mm 5 1/8" for upper roots right curved tip figure 39	04060414017311
DN3155	CRYER root elevator 130mm 5 1/8" for upper roots left curved tip figure 40	04060414017328
DN3156	LECLUSE root elevator 115mm 4 1/2" tapered jaw right curved with T-Handle figure 1	04060414017335
DN3160	HYLIN root elevator straight jaw width 4.5mm figure 1	04060414017342
DN3162	HYLIN root elevator 140mm 5 1/2" left angled jaw width 3.0mm figure 3L	04060414017359
DN3163	HYLIN root elevator 140mm 5 1/2" right angled jaw width 3.0mm figure 4R	04060414017366
DN3165	POTT root elevator 150mm 6" left angled figure 1	04060414017373
DN3166	POTT root elevator 150mm 6" right angled figure 2	04060414017380
DN3170	WINTER root elevator 110mm 4 1/4" left angled with T-Handle figure 11L	04060414017397
DN3171	WINTER root elevator 110mm 4 1/4" right angled with T-Handle figure 11R	04060414017403



PHA-FORCE – Kraftausübende Instrumente
PHA-FORCE – Force Exerting instruments

Annex I zur Konformitätserklärung: Zweckbestimmung

Annex I to the declaration of conformity: Intended Purpose

PA-ABRAS12B Handbohrapparate: <i>Drill manual:</i> Beispiel / example: KN5900 	Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zum Bohren oder Fräsen von Knochen oder hartem Gewebe in Verbindung mit einem geeigneten Bohrwerkzeug.	<i>Reusable surgical invasive instrument for transient use on humans for drilling or milling bones or hard tissue in conjunction with a suitable drilling tool.</i>
PA-ACC11 Hämmer, chirurgisch: <i>Mallets, surgical:</i> Beispiel / example: KN2070 	Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zur Ausübung von Schlägen auf andere Instrumente wie Meißel oder Ausschläger.	<i>Reusable surgical invasive instrument for transient use on humans for striking other instruments such as chisels or knives.</i>
PA-ACC12 Stößel und Einschläger: <i>Pestle and impactor:</i> Beispiel / example: KN2230 	Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zum Einbringen und Verdichten von Knochenspänen im Rahmen der orthopädischen Chirurgie.	<i>Reusable surgical invasive instrument for transient use on humans for inserting and compressing bone chips in the context of orthopedic surgery.</i>
PA-ACC14 Stopfer dental: <i>Tampers dental:</i> Beispiel / example: DN0100 	Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen. Füll- und Stopfinstrument zur Einbringung von Tamponade in den Wundbereich und zur Legung von Füllungen im zahnmedizinischen Bereich.	<i>Reusable surgical invasive instrument for transient use on humans. Filling and stuffing instrument for inserting tamponade into the wound area and for placing fillings in the dental field.</i>
PA-ACC27 Schlüssel, Schraubendreher: <i>Wrenches and screwdriver:</i> Beispiel / example: MN2280 	Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zum Ein- oder Ausdrehen von Schrauben in chirurgischen Instrumenten oder Knochen.	<i>Reusable surgical invasive instrument for transient use on humans for screwing in or out screws in surgical instruments or bones.</i>
PA-CUT23 Drahtzangen: <i>Wire pliers:</i> Beispiel / example: KN6541 	Wiederverwendbares nicht aktives chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zum Schneiden und Halten von Drähten oder Blechen für die Orthopädie.	<i>Reusable surgical invasive instrument for transient use on human beings for cutting or holding wires or plates for orthopaedic surgery.</i>
PA-HOOKS07 Knochenheber und Elevatorien: <i>Bone lever and elevators:</i> Beispiel / example: KN0310 	Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zum Anheben, Positionieren oder Aufhebeln von Knochen, anderen anatomischen Strukturen oder chirurgischem Material in der orthopädischen Chirurgie.	<i>Reusable surgical invasive instrument for transient use on humans used during orthopaedic surgery to lift, position, or pry up bone, other anatomic structures or surgical material.</i>



PHA-FORCE – Kraftausübende Instrumente
PHA-FORCE – Force Exerting instruments

Annex I zur Konformitätserklärung: Zweckbestimmung

Annex I to the declaration of conformity: Intended Purpose

PA-HOOKS11

Elevatorium, sonstige:

Elevator:

Beispiel / example:

NS2070



Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zur Anhebung von Gewebe oder Knochenfragmenten, um eine Reposition vorzunehmen oder einen eingedrückten Knochen anzuheben.

Reusable surgical invasive instrument for transient use on humans to lift tissue or bone fragments to make a reduction or to lift a dented bone.

PA-HOOKS12

Wurzelheber ,dental:

Root elevator, dental:

Beispiel / example:

DN3130



Wiederverwendbares chirurgisch invasives Instrument zur vorübergehenden Anwendung am Menschen zum Anheben von Zahnwurzeln.

Reusable surgical invasive instrument for transient use on humans for lifting tooth roots.

Společnost

ASANUS Medizintechnik GmbH
take off Gewerbepark 2
78579 Neuhausen ob Eck
Německo (Kreis Tuttlingen)
SRN: DE-MF-000005540

tímto prohlašuje na základě výhradní odpovědnosti při aplikování článku 120 nařízení (EU) 2017/745, že následující zdravotnické prostředky (viz příloha tohoto prohlášení o shodě)

Popis: Nástroje působící silou, paličky, kladívka, šroubováky atd.

Základní UDI-DI: viz připojený seznam výrobků
Třída rizika: IR
Pravidlo: viz připojený seznam výrobků
Určený účel: viz Příloha I k tomuto prohlášení

splňují požadavky Přílohy IX, kapitola I a III nařízení (EU) 2017/745 (MDR).

Postup posouzení shody je prováděn ve spolupráci s oznámeným subjektem DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt nad Mohanem, identifikační číslo 0297.

Výrobky proto mohou nést značení CE.

Aplikované harmonizované normy, vnitrostátní předpisy či jiné normativní dokumenty:

- Nařízení (EU) 2017/745 (MDR) (= nařízení o ZP)
- DIN EN ISO 13485:2021
- Medizinproduktegesetz – MPDG (vnitrostátní legislativa)

Toto prohlášení platí do 31. 12. 2028

Datum: 27.05.2024

Podpis nečitelný, firemní razítko spol. ASANUS
Podpis

Přiřazené výrobky:

Skupiny výrobků	Č. EMDN	NÁZEV EMDN	Základní UDI-DI	Riziko	Pravidlo
\$PA-ABRAS12B	Z12130503	ORTHOPAEDIC SURGICAL DRILLS	4060414PA-ABRAS12B3Z	IR	6 - 2
\$PA-ACC11	REF	Name	UDI/GTIN	IR	6 - 2
	L0903	ORTHOPEDIC SURGERY HAMMERS, REUSABLE	4060414PA-ACC1136		
	REF	Name	UDI/GTIN		
	KN2000F	NOVOTEX ferrozell mallet 250mm 10" head Ø42mm small version of KN2010	04060414241501		
	KN2010F	NOVOTEX ferrozell mallet 270mm 10 3/4" head Ø48mm	04060414241518		
	KN2020F	Ferrozell mallet 265mm 10 1/2" head Ø50mm	04060414241525		
	KN2039	Mini mallet 165mm 6 1/2" head Ø20mm lead filled extra heavy 80g	04060414096484		



PHA-FORCE – Nástroje působící silou

Příloha I k přihlášení o shodě: Určený účel

PA-ABRAS12B Handbohrapparate: Drill manual: Beispiel / example: KN5900 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k vrtání nebo frézování kostí či tvrdé tkáně ve spojení s vhodnou vrtačkou.
PA-ACC11 Hämmer, chirurgisch: Mallets, surgical: Beispiel / example: KN2070 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k poklepání na jiné nástroje jako např. dláta nebo nože.
PA-ACC12 Stößel und Einschläger: Pestle and impactor: Beispiel / example: KN2230 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k implantaci kostních štěpů při ortopedické operaci.
PA-ACC14 Stopfer dental: Tampers dental: Beispiel / example: DN0100 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí. Nástroj na zavádění tamponády v oblasti ošetřování ran a zatlačení výplní ve stomatologii.
PA-ACC27 Schlüssel, Schraubendreher: Wrenches and screwdriver: Beispiel / example: MN2280 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k zašroubování nebo vyšroubování šroubů v chirurgických nástrojích nebo kostech.
PA-CUT23 Drahtzangen: Wire pliers: Beispiel / example: KN6541 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí ke štípání nebo držení drátů či destiček při ortopedické operaci.
PA-HOOKS07 Knochenhebel und Elevatorien: Bone lever and elevators: Beispiel / example: KN0310 		Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí používaný během ortopedické operace ke zvednutí, umístění nebo uvolnění kosti, jiných anatomických struktur nebo chirurgického materiálu.



PHA-FORCE – Nástroje působící silou

Příloha I k přihlášení o shodě: Určený účel

PA-HOOKS11 Elevatorium, sonstige: <i>Elevator:</i> Beispiel / example: NS2070 		<i>Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k uvolnění tkáně nebo úlomků kosti při provedení repozice nebo k uvolnění promáčklé kosti.</i>
PA-HOOKS12 Wurzelheber ,dental: <i>Root elevator, dental:</i> Beispiel / example: DN3130 		<i>Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k extrakci kořenů zubů.</i>

PŘEKLADATELSKÁ DOLOŽKA

Já, Mgr. Alice Tejkalová, jsem provedla překladatelský úkon jako tlumočnice a překladatelka jmenovaná podle zákona č. 36/1967 Sb. rozhodnutím předsedy Krajského soudu v Praze ze dne 15. listopadu 1991, č.j. Spr. 698/91, pro jazyk český a anglický, zapsaná v seznamu soudních tlumočnicků a soudních překladatelů vedeném Ministerstvem spravedlnosti ČR, v souladu s § 44 zákona č. 354/2019 Sb., o soudních tlumočnících a soudních překladatelích.

Stvrzuji, že překlad souhlasí s textem připojené listiny.

Úkon je zapsán v evidenci úkonů pod číslem

137311/2024-6

dne **17. 6. 2024.**

Translator's Clause

I, Mgr. Alice Tejkalová, translated the document as an interpreter and translator to English appointed by the decision of the Regional Court in Prague on November 15, 1991, file. No. Spr. 698/91, under Act No. 36/1967 Sb., and entered in the Register of Court Interpreters and Court Translators maintained by the Ministry of Justice of the Czech Republic in compliance with Act No. 354/2019 Sb., on Court Interpreters and Court Translators, Section 44.

I hereby certify that this is a true and accurate translation of the original document.

The translation is entered in the translation register under No.

137311/2024-6

on **17/06/2024.**

Mgr. Alice Tejkalová

Mgr. Alice Tejkalová

