

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:** Weitende Instrumente Sonden, Dilatatoren

**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
- Medizinprodukte-Durchführungsgesetz - MPDG

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:** Dilating instruments probes, dilators

**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
- Medizinprodukte-Durchführungsgesetz - MPDG (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-ACC10     | L070805 | VASCULAR TUNNELLERS, REUSABLE                                                 | 4060414PA-ACC1034 | IR   | 6 - 2 |
|                | REF     | Name                                                                          | UDI/GTIN          |      |       |
|                | GF3920  | Tunnelling forceps 500mm 19 2/3"                                              | 04060414063660    |      |       |
|                | GF6037  | Tube for tunneling instrument 510mm 20 1/4" slightly curved                   | 04060414065671    |      |       |
|                | GF6038  | Bulldog mandrin for tunneling instrument 590mm 23 1/2" slightly curved        | 04060414065688    |      |       |
|                | GF6039  | Tunneling instrument set 590mm 23 1/2" consisting of GF6037 GF6038 and GF6042 | 04060414065695    |      |       |

# EU Konformitätserklärung

## EC Declaration of conformity



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|        |                                                                                     |                |
|--------|-------------------------------------------------------------------------------------|----------------|
| GF6040 | Tunneling instrument set 740mm 29 1/2"<br>consisting of<br>GF6043 GF6041 and GF6042 | 04060414065701 |
| GF6041 | Bulldog mandrin for tunneling<br>instrument 740mm 29 1/2"<br>slightly curved        | 04060414065718 |
| GF6042 | Olive for tunneling instrument                                                      | 04060414065725 |
| GF6043 | Tube for tunneling instrument 660mm<br>26 1/4"<br>slightly curved                   | 04060414065732 |
| GF6045 | Tunneling instrument set 810mm 32"<br>consisting of<br>GF6047 GF6046 and GF6042     | 04060414065749 |
| GF6046 | Bulldog mandrin for tunneling<br>instrument 810mm 32"<br>slightly curved            | 04060414065756 |
| GF6047 | Tube for tunneling instrument 720mm<br>28 3/4"<br>slightly curved                   | 04060414065763 |

\$PA-END01 A0705 CAPS OR OBTURATORS 4060414PA-END016Z IR 6 - 2

|        |                                                                                                        |                |
|--------|--------------------------------------------------------------------------------------------------------|----------------|
| REF    | Name                                                                                                   | UDI/GTIN       |
| TR1180 | Conical obturator diam.10,0 mm<br>100 mm 4" long                                                       | 04060414231939 |
| TR3034 | Cone obturator for trocars                                                                             | 04060414236712 |
| TR3039 | Trocar conical tip, diameter 5,5mm<br>tip slightly blunt<br>165mm working length, 250 mm total lengt   | 04060414230819 |
| TR3040 | Trocar conical tip, diam.5,5mm<br>tip slightly blunt, 200 mm use length,<br>285mm 11 1/4" total length | 04060414237122 |

\$PA-SOND01 L0311 PROBES AND EXPLORERS, REUSABLE 4060414PA-SOND01M3 IR 6 - 2

|        |                                                                                          |                |
|--------|------------------------------------------------------------------------------------------|----------------|
| REF    | Name                                                                                     | UDI/GTIN       |
| EN0100 | Palpation probe Ø5.0mm graduated<br>working length 300mm 12"                             | 04060414023435 |
| EN0101 | Palpation probe Ø5.0mm graduated<br>working length 330mm 13"                             | 04060414023442 |
| EN0102 | Palpation probe Ø5.0mm graduated<br>working length 400mm 15 3/4"                         | 04060414023459 |
| EN0103 | Palpation probe Ø5.0mm graduated<br>working length 450mm 17 3/4"                         | 04060414023466 |
| EN4016 | ARTICU LINE graduated probe 225mm 9"<br>2.5mm without handle<br>working length universal | 04060414035001 |
| EN4018 | ARTICU LINE graduated probe 225mm 9"<br>3.5mm without handle<br>working length universal | 04060414035018 |

|          |                                                                                          |                |
|----------|------------------------------------------------------------------------------------------|----------------|
| EN4020   | ARTICU LINE graduated probe 225mm 9"<br>4.0mm without handle<br>working length universal | 04060414035025 |
| EN4022   | ARTICU LINE graduated probe 225mm 9"<br>5.0mm without handle<br>working length universal | 04060414035032 |
| EN4024   | ARTICU LINE hook probe graduated<br>3.0mm with triangle handle<br>working length 110mm   | 04060414035049 |
| EN4026   | ARTICU LINE hook probe graduated<br>4.0mm with triangle handle<br>working length 110mm   | 04060414035056 |
| EN4028   | ARTICU LINE hook probe graduated<br>5.0mm with triangle handle<br>working length 110mm   | 04060414035063 |
| EOR1360  | DALIA JOBSON-HORNE ear probe 140mm 5<br>1/4"                                             | 04060414411638 |
| EOR1370  | DALIA JOBSON-HORNE ear probe 180mm 7<br>1/8"                                             | 04060414338683 |
| ESD0100  | DALIA Grooved director 130mm 5 1/8"<br>straight                                          | 04060414048551 |
| ESD0480  | DALIA Probe double ended 200mm 8" Ø2.0mm                                                 | 04060414048568 |
| GL0370   | HELLER papillotom probe 200mm 8"<br>Ø6.0mm                                               | 04060414070361 |
| GL0380   | HELLER papillotom probe 200mm 8"<br>Ø8.0mm                                               | 04060414070378 |
| GL0390   | HELLER papillotom probe 200mm 8"<br>Ø10.0mm                                              | 04060414070385 |
| HA1650   | SEIFFERT salival probe 180mm 7 1/8"<br>malleable Ø1.0mm                                  | 04060414078596 |
| MN1570   | JACOBSON ball probe 185mm 7 1/4"<br>angled                                               | 04060414114331 |
| MN1580   | JACOBSON double ball probe 185mm 7 1/4"<br>with micro ball ends                          | 04060414114348 |
| MN1831   | RHOTON micro ball probe 190mm 7 1/2"<br>90° angled                                       | 04060414115154 |
| MN1831-1 | RHOTON micro ball probe 175mm 7"<br>90° angled                                           | 04060414115161 |
| MN3580   | TOENNIS grooved director 240mm 9 1/2"<br>double ended                                    | 04060414118063 |
| OR1310   | TUMARKIN ear probe 152mm 6"<br>package with 50 pieces                                    | 04060414154221 |
| OR1360   | JOBSON-HORNE ear probe 140mm 5 1/4"                                                      | 04060414154290 |

|        |                                                                   |                |
|--------|-------------------------------------------------------------------|----------------|
| OR1370 | JOBSON-HORNE ear probe 180mm 7 1/8"                               | 04060414154306 |
| SD0099 | Grooved director 115mm 4 1/2" straight                            | 04060414179651 |
| SD0100 | Grooved director 130mm 5 1/8" straight                            | 04060414179668 |
| SD0110 | Grooved director 145mm 5 3/4" straight                            | 04060414179675 |
| SD0120 | Grooved director 160mm 6 1/4" straight                            | 04060414179682 |
| SD0121 | Grooved director 180mm 7 1/8" straight                            | 04060414179699 |
| SD0122 | Grooved director 200mm 8" straight                                | 04060414179705 |
| SD0130 | DOYEN grooved director 145mm 5 3/4"<br>curved sharp               | 04060414179712 |
| SD0140 | NELATON grooved director 160mm 6 1/4"<br>curved blunt             | 04060414179729 |
| SD0149 | Grooved director 130mm 5 1/8" straight<br>with ball tip Ø3.3mm    | 04060414179743 |
| SD0150 | Grooved director 140mm 5 1/2" straight<br>with ball tip Ø3.3mm    | 04060414179750 |
| SD0151 | Grooved director 160mm 6 1/4" straight<br>with ball tip Ø3.3mm    | 04060414179767 |
| SD0152 | Grooved director 180mm 7 1/8" straight<br>with ball tip Ø3.3mm    | 04060414179774 |
| SD0160 | BRODIE grooved director 200mm 8"<br>straight with ball tip Ø3.5mm | 04060414179781 |
| SD0210 | Director with wire loop 190m 7 1/2"<br>malleable                  | 04060414179835 |
| SD0218 | Button probe with eye 115mm 4 1/2"<br>Ø2.0mm                      | 04060414179842 |
| SD0219 | Button probe with eye 130mm 5 3/4"<br>Ø2.0mm                      | 04060414179859 |
| SD0220 | Button probe with eye 145mm 5 3/4"<br>Ø2.0mm                      | 04060414179866 |
| SD0230 | Button probe with eye 160mm 6 1/4"<br>Ø2.0mm                      | 04060414179873 |
| SD0235 | Button probe with eye 180mm 7 1/8"<br>Ø2.0mm                      | 04060414179880 |
| SD0240 | Button probe with eye 200mm 8"<br>Ø2.0mm                          | 04060414179897 |
| SD0245 | Button probe with eye 250mm 7 1/8"<br>Ø2.0mm                      | 04060414179903 |
| SD0250 | Myrtle leaf probe 145mm 5 3/4"<br>Ø1.5mm                          | 04060414179910 |
| SD0253 | FISH probe 145mm 5 3/4" Ø2.0mm                                    | 04060414179927 |

|        |                                                                              |                |
|--------|------------------------------------------------------------------------------|----------------|
| SD0254 | FISH probe 180mm 7 1/8" Ø2.0mm                                               | 04060414179934 |
| SD0259 | Myrtle leaf probe 115mm 4 1/2" Ø2.0mm                                        | 04060414179941 |
| SD0260 | Myrtle leaf probe 130mm 5 1/8" Ø2.0mm                                        | 04060414179958 |
| SD0270 | Myrtle leaf probe 145mm 5 3/4" Ø2.0mm                                        | 04060414179965 |
| SD0280 | Myrtle leaf probe 160mm 6 1/4" Ø2.0mm                                        | 04060414179972 |
| SD0290 | Myrtle leaf probe 180mm 7 1/8" Ø2.0mm                                        | 04060414179989 |
| SD0300 | Myrtle leaf probe 200mm 8" Ø2.0mm                                            | 04060414179996 |
| SD0310 | Probe double ended 190mm Ø3.0mm malleable with hole                          | 04060414180008 |
| SD0315 | PLASTIC PROBE 1,0MM LENGTH 200 MM                                            | 04060414180015 |
| SD0316 | PLASTIC PROBE 1,5MM LENGTH 200 MM                                            | 04060414180022 |
| SD0317 | PLASTIC PROBE 2,0MM LENGTH 200 MM                                            | 04060414180039 |
| SD0318 | PLASTIC PROBE 2,5MM LENGTH 200 MM                                            | 04060414180046 |
| SD0320 | Double ended probe malleable, tip Ø 3,5 mm 250 mm, 10" total length          | 04060414180053 |
| SD0330 | Double ended probe tin, malleable, tip Ø 3,5 mm 300 mm, 12" total length     | 04060414180060 |
| SD0340 | Double ended probe, TIN, 4,0 mm diameter malleable, 400 mm, 16" total length | 04060414180077 |
| SD0350 | Button probe 300mm 12" Ø1.5mm with hexagonal handle                          | 04060414180084 |
| SD0360 | Button probe 300mm 12" Ø2.0mm with hexagonal handle                          | 04060414180091 |
| SD0370 | Button probe 300mm 12" Ø2.5mm with hexagonal handle                          | 04060414180107 |
| SD0376 | Probe double ended mini 80mm 2 1/4" Ø2.0+1.6mm                               | 04060414180114 |
| SD0377 | Probe double ended 115mm 4 1/2" Ø1.5+1.0mm                                   | 04060414180121 |
| SD0378 | Probe double ended 115mm 4 1/2" Ø1.0mm                                       | 04060414180138 |

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|--------|-----------------------------------------------------|----------------|
| SD0379 | Probe double ended 130mm 5 1/8" Ø1.0mm              | 04060414180145 |
| SD0380 | Probe double ended 145mm 5 3/4" Ø1.0mm              | 04060414180152 |
| SD0381 | Probe double ended 160mm 6 1/4" Ø1.0mm              | 04060414180169 |
| SD0382 | Probe double ended 180mm 7 1/8" Ø1.0mm              | 04060414180176 |
| SD0383 | Probe double ended 200mm 8" Ø1.0mm                  | 04060414180183 |
| SD0384 | Probe double ended 250mm 10" Ø1.0mm                 | 04060414180190 |
| SD0389 | Probe double ended 115mm 4 1/2" Ø1.5mm              | 04060414180206 |
| SD0390 | Probe double ended 130mm 5 1/8" Ø1.5mm              | 04060414180213 |
| SD0400 | Probe double ended 145mm 5 3/4" Ø1.5mm              | 04060414180220 |
| SD0410 | Probe double ended 160mm 6 1/4" Ø1.5mm              | 04060414180244 |
| SD0420 | Probe double ended 180mm 7 1/8" Ø1.5mm              | 04060414180251 |
| SD0424 | Probe double ended 160mm 6 1/4" Ø1.5mm<br>malleable | 04060414180268 |
| SD0430 | Probe double ended 200mm 8" Ø1.5mm                  | 04060414180275 |
| SD0440 | Probe double ended 250mm 10" Ø1.5mm                 | 04060414180282 |
| SD0448 | Probe double ended 115mm 4 1/2" Ø2.0mm              | 04060414180299 |
| SD0449 | Probe double ended 130mm 5 1/8" Ø2.0mm              | 04060414180305 |
| SD0450 | Probe double ended 145mm 5 3/4" Ø2.0mm              | 04060414180312 |
| SD0452 | Probe 130mm 5 1/8" Ø2.0mm<br>flat sharp end         | 04060414180329 |
| SD0453 | Probe 145mm 5 3/4" Ø2.0mm<br>flat sharp end         | 04060414180336 |
| SD0454 | Probe 160mm 6 1/4" Ø2.0mm<br>flat sharp end         | 04060414180343 |
| SD0460 | Probe double ended 160mm 6 1/4" Ø2.0mm              | 04060414180350 |
| SD0470 | Probe double ended 180mm 7 1/8" Ø2.0mm              | 04060414180367 |
| SD0480 | Probe double ended 200mm 8" Ø2.0mm                  | 04060414180374 |
| SD0485 | Probe double ended 250mm 10" Ø2.0mm                 | 04060414180381 |
| SD0490 | Probe double ended 300mm 12" Ø2.0mm                 | 04060414180398 |
| SD0500 | STACKE probe 105mm 4" silver<br>Ø 1.0mm             | 04060414180404 |
| SD0520 | KILLIAN nasal pobe 165mm 6 1/2"                     | 04060414180411 |

|             |                                                                   |                          |                    |    |       |
|-------------|-------------------------------------------------------------------|--------------------------|--------------------|----|-------|
| \$PA-SOND02 | L031101                                                           | FISTULA PROBES, REUSABLE | 4060414PA-SOND02M5 | IR | 6 - 2 |
| REF         | Name                                                              | UDI/GTIN                 |                    |    |       |
| RK0260      | Fistula probe and Krypt hook<br>240mm 9 1/2" tip curved downwards | 04060414164107           |                    |    |       |

|             |                                                                                                 |                    |
|-------------|-------------------------------------------------------------------------------------------------|--------------------|
| SD0140I     | Fistula probe, curved, for the use of monopolar knife elektrodes<br>160 mm, 6 1/4" total length | 04060414179736     |
| SD0170      | LOCKHART-MUMMERY fistula probe 160mm<br>6 1/2" straight                                         | 04060414179798     |
| SD0180      | LOCKHART-MUMMERY fistula probe 160mm<br>6 1/2" 45° curved                                       | 04060414179804     |
| SD0190      | LOCKHART-MUMMERY fistula probe 160mm<br>6 1/2" 90° curved                                       | 04060414179811     |
| SD0200      | LOCKHART-MUMMERY fistula probe 160mm<br>retrograde 6 1/2" 90° curved                            | 04060414179828     |
| \$PA-SOND04 | L04100101 BILIARY SURGICAL PROBES, REUSABLE                                                     | 4060414PA-SOND04M9 |
| REF         | Name                                                                                            | UDI/GTIN           |
| EGL0440     | DALIA DESJARDINS gall stone scoop 300mm<br>12" Ø6.0mm figure 1                                  | 04060414019087     |
| EGL0450     | DALIA DESJARDINS gall stone scoop 300mm<br>12" Ø7.0mm figure 2                                  | 04060414019094     |
| GL0160      | MOYNIHAN gall stone probe and -scoop<br>340mm 13 1/2" of tin malleable tip Ø5mm                 | 04060414070200     |
| GL0170      | OCHSNER gall duct probe 405mm 16"<br>Ø3.5mm flexible                                            | 04060414070217     |
| GL0410      | DESJARDINS gall duct probe<br>285mm 11 1/4" button Ø3.8mm flexible                              | 04060414070408     |
| GL0420      | DESJARDINS gall duct probe<br>285mm 11 1/4" button Ø5.3mm flexible                              | 04060414070415     |
| GL0430      | DESJARDINS gall duct probe<br>285mm 11 1/4" button Ø6.8mm flexible                              | 04060414070422     |
| GL0440      | DESJARDINS gall stone scoop 300mm 12"<br>Ø6.0mm<br>figure 1                                     | 04060414070439     |
| GL0450      | DESJARDINS gall stone scoop 300mm 12"<br>Ø7.0mm<br>figure 2                                     | 04060414070446     |
| GL0460      | DESJARDINS gall stone scoop 300mm 12"<br>Ø8.0mm<br>figure 3                                     | 04060414070453     |
| GL0470      | DESJARDINS gall stone scoop 300mm 12"<br>Ø9.0mm<br>figure 4                                     | 04060414070460     |
| GL0480      | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø3.0mm                                       | 04060414070477     |
| GL0490      | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø4.0mm                                       | 04060414070484     |
| GL0500      | BAKES gall duct probe 190mm 7 1/2"                                                              | 04060414070491     |

curved rigid Ø5.0mm

|        |                                                                                         |                |
|--------|-----------------------------------------------------------------------------------------|----------------|
| GL0510 | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø6.0mm                               | 04060414070507 |
| GL0520 | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø7.0mm                               | 04060414070514 |
| GL0530 | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø8.0mm                               | 04060414070521 |
| GL0540 | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø9.0mm                               | 04060414070538 |
| GL0550 | BAKES gall duct probe 190mm 7 1/2"<br>curved rigid Ø10.0mm                              | 04060414070545 |
| GL0560 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 2.8mm<br>figure 000 | 04060414070552 |
| GL0570 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 3.4mm<br>figure 00  | 04060414070569 |
| GL0580 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 4.3mm<br>figure 0   | 04060414070576 |
| GL0590 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 5.5mm<br>figure 1   | 04060414070583 |
| GL0600 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 6.7mm<br>figure 2   | 04060414070590 |
| GL0610 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 8.0mm<br>figure 3   | 04060414070606 |
| GL0620 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 11.0mm<br>figure 4  | 04060414070613 |
| GL0630 | LUER-KOERTE gall stone scoop 320mm<br>12 3/4" malleable shaft width 15.0mm<br>figure 5  | 04060414070620 |

|             |                                                                            |                             |                    |    |       |
|-------------|----------------------------------------------------------------------------|-----------------------------|--------------------|----|-------|
| \$PA-SOND07 | L070802                                                                    | VASCULAR DILATORS, REUSABLE | 4060414PA-SOND07MF | IR | 6 - 2 |
| REF         | Name                                                                       | UDI/GTIN                    |                    |    |       |
| EN0104      | Dilatation-set complete<br>from 5 to 10mm<br>consisting of pin and sleeve  | 04060414023473              |                    |    |       |
| EN0105      | Dilatation-set complete<br>from 5 to 11mm<br>consisting of pin and sleeve  | 04060414023480              |                    |    |       |
| EN0106      | Dilatation-set complete<br>from 11 to 15mm<br>consisting of pin and sleeve | 04060414023497              |                    |    |       |



|        |                                                                                  |                |
|--------|----------------------------------------------------------------------------------|----------------|
| EN0107 | Dilatation-set complete<br>from 10 to 15mm<br>consisting of pin and sleeve       | 04060414023503 |
| EN0108 | Dilatation-set complete<br>from 5 to 15mm<br>consisting of pin and sleeve        | 04060414023510 |
| EN0109 | Dilatation-set complete<br>from 11 to 20mm<br>consisting of pin and sleeve       | 04060414023527 |
| EN0110 | Dilatation-set complete<br>from 10 to 20mm<br>consisting of pin and sleeve       | 04060414023534 |
| EN0111 | Dilatation-set complete<br>from 5 to 20mm<br>consisting of pin and sleeve        | 04060414023541 |
| GF0241 | GARRET vascular dilator 140mm 5 1/2"<br>Ø1.0mm malleable<br>round knurled handle | 04060414050417 |
| GF0242 | GARRET vascular dilator 140mm 5 1/2"<br>Ø1.5mm malleable<br>round knurled handle | 04060414050424 |
| GF0243 | GARRET vascular dilator 140mm 5 1/2"<br>Ø2.0mm malleable<br>round knurled handle | 04060414050431 |
| GF0244 | GARRET vascular dilator 140mm 5 1/2"<br>Ø2.5mm malleable<br>round knurled handle | 04060414050448 |
| GF0245 | GARRET vascular dilator 140mm 5 1/2"<br>Ø3.0mm malleable<br>round knurled handle | 04060414050455 |
| GF0246 | GARRET vascular dilator 140mm 5 1/2"<br>Ø3.5mm malleable<br>round knurled handle | 04060414050462 |
| GF0247 | GARRET vascular dilator 140mm 5 1/2"<br>Ø4.0mm malleable<br>round knurled handle | 04060414050479 |
| GF0248 | GARRET vascular dilator 140mm 5 1/2"<br>Ø4.5mm malleable<br>round knurled handle | 04060414050486 |
| GF0249 | GARRET vascular dilator 140mm 5 1/2"<br>Ø5.0mm malleable<br>round knurled handle | 04060414050493 |
| GF3831 | Cross-section-sizer 220mm 8 3/4"<br>Ø18/20mm                                     | 04060414063448 |
| GF3832 | Cross-section-sizer 220mm 8 3/4"<br>Ø19/21mm                                     | 04060414063455 |
| GF3833 | Cross-section-sizer 220mm 8 3/4"<br>Ø22/24mm                                     | 04060414063462 |

|        |                                                                                 |                |
|--------|---------------------------------------------------------------------------------|----------------|
| GF3834 | Cross-section-size 220mm 8 3/4"<br>Ø23/25mm                                     | 04060414063479 |
| GF3835 | Cross-section-size 220mm 8 3/4"<br>Ø26/28mm                                     | 04060414063486 |
| GF3836 | Cross-section-size 220mm 8 3/4"<br>Ø27/29mm                                     | 04060414063493 |
| GF3837 | Cross-section-size 220mm 8 3/4"<br>Ø30/32mm                                     | 04060414063509 |
| GF4120 | MOHR ruler 300mm 12"<br>Ø12mm working area 79mm                                 | 04060414063905 |
| GF4121 | MOHR ruler 300mm 12"<br>Ø12mm working area 113mm                                | 04060414063912 |
| GF4122 | MOHR ruler 300mm 12"<br>Ø14mm working area 154mm                                | 04060414063929 |
| GF4123 | MOHR ruler 300mm 12"<br>Ø16mm working area 201mm                                | 04060414063936 |
| GF4124 | MOHR ruler 300mm 12"<br>Ø18mm working area 254mm                                | 04060414063943 |
| GF4125 | MOHR ruler 300mm 12"<br>Ø20mm working area 314mm                                | 04060414063950 |
| GF4126 | MOHR ruler 300mm 12"<br>Ø22mm working area 380mm                                | 04060414063967 |
| GF4502 | BROOK dilator<br>spread 8-20mm complete with handle                             | 04060414064353 |
| GF4530 | TUBBS dilator<br>spread 9-45mm<br>working length 180 mm 7 1/8"                  | 04060414064407 |
| GF4531 | TUBBS dilator<br>spread 8-42mm<br>working length 180 mm 7 1/8"                  | 04060414064414 |
| GF4541 | TUBBS dilator<br>spread 9-45mm                                                  | 04060414064438 |
| GF4546 | GERBODE dilator<br>spread 9-45mm                                                | 04060414064445 |
| GF4547 | COOLEY dilator<br>spread 9-40mm                                                 | 04060414064452 |
| GF4550 | COOLEY-DeBAKEY dilator<br>spread 7-30mm                                         | 04060414064469 |
| GF5100 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø0.5mm malleable with hexagonal handle | 04060414064773 |
| GF5101 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø1.0mm malleable with hexagonal handle | 04060414064780 |
| GF5102 | DeBAKEY vascular dilator 190mm 7 1/2"                                           | 04060414064797 |

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|        | Ø1.5mm malleable with hexagonal handle                                           |                |
| GF5103 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø2.0mm malleable with hexagonal handle  | 04060414064803 |
| GF5104 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø2.5mm malleable with hexagonal handle  | 04060414064810 |
| GF5105 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø3.0mm malleable with hexagonal handle  | 04060414064827 |
| GF5106 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø3.5mm malleable with hexagonal handle  | 04060414064834 |
| GF5107 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø4.0mm malleable with hexagonal handle  | 04060414064841 |
| GF5108 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø4.5mm malleable with hexagonal handle  | 04060414064858 |
| GF5109 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø5.0mm malleable with hexagonal handle  | 04060414064872 |
| GF5111 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø6.0mm malleable with hexagonal handle  | 04060414064889 |
| GF5113 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø7.0mm malleable with hexagonal handle  | 04060414064896 |
| GF5115 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø8.0mm malleable with hexagonal handle  | 04060414064902 |
| GF5117 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø9.0mm malleable with hexagonal handle  | 04060414064919 |
| GF5119 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø10.0mm malleable with hexagonal handle | 04060414064940 |
| GF5121 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø11.0mm malleable with hexagonal handle | 04060414064964 |
| GF5123 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø12.0mm malleable with hexagonal handle | 04060414064971 |
| GF5125 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø13.0mm malleable with hexagonal handle | 04060414064988 |
| GF5130 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø0.5mm malleable with hexagonal handle | 04060414064995 |
| GF5131 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø1.0mm malleable with hexagonal handle | 04060414065008 |
| GF5132 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø1.5mm malleable with hexagonal handle | 04060414065015 |
| GF5133 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø2.0mm malleable with hexagonal handle | 04060414065022 |
| GF5134 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø2.5mm malleable with hexagonal handle | 04060414065039 |
| GF5135 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø3.0mm malleable with hexagonal handle | 04060414065046 |

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| GF5136 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø3.5mm malleable with hexagonal handle  | 04060414065053 |
| GF5137 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø4.0mm malleable with hexagonal handle  | 04060414065060 |
| GF5138 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø4.5mm malleable with hexagonal handle  | 04060414065077 |
| GF5139 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø5.0mm malleable with hexagonal handle  | 04060414065084 |
| GF5141 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø6.0mm malleable with hexagonal handle  | 04060414065091 |
| GF5143 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø7.0mm malleable with hexagonal handle  | 04060414065107 |
| GF5145 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø8.0mm malleable with hexagonal handle  | 04060414065114 |
| GF5147 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø9.0mm malleable with hexagonal handle  | 04060414065121 |
| GF5149 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø10.0mm malleable with hexagonal handle | 04060414065138 |
| GF5151 | DeBAKEY vascular dilator 380mm 15 1/8"<br>Ø11.0mm malleable with hexagonal handle | 04060414065145 |
| GF5170 | BAKES bile duct dilator 300mm 12"<br>Ø0.5mm malleable with hexagonal handle       | 04060414065183 |
| GF5171 | BAKES bile duct dilator 300mm 12"<br>Ø1.0mm malleable with hexagonal handle       | 04060414065190 |
| GF5172 | BAKES bile duct dilator 300mm 12"<br>Ø1.5mm malleable with hexagonal handle       | 04060414065206 |
| GF5173 | BAKES bile duct dilator 300mm 12"<br>Ø2.0mm malleable with hexagonal handle       | 04060414065213 |
| GF5174 | BAKES bile duct dilator 300mm 12"<br>Ø2.5mm malleable with hexagonal handle       | 04060414065220 |
| GF5175 | BAKES bile duct dilator 300mm 12"<br>Ø3.0mm malleable with hexagonal handle       | 04060414065237 |
| GF5176 | BAKES bile duct dilator 300mm 12"<br>Ø3.5mm malleable with hexagonal handle       | 04060414065244 |
| GF5177 | BAKES bile duct dilator 300mm 12"<br>Ø4.0mm malleable with hexagonal handle       | 04060414065251 |
| GF5178 | BAKES bile duct dilator 300mm 12"<br>Ø4.5mm malleable with hexagonal handle       | 04060414065268 |
| GF5179 | BAKES bile duct dilator 300mm 12"<br>Ø5.0mm malleable with hexagonal handle       | 04060414065275 |
| GF5181 | BAKES bile duct dilator 300mm 12"<br>Ø6.0mm malleable with hexagonal handle       | 04060414065282 |

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| GF5183 | BAKES bile duct dilator 300mm 12"<br>Ø7.0mm malleable with hexagonal handle     | 04060414065299 |
| GF5185 | BAKES bile duct dilator 300mm 12"<br>Ø8.0mm malleable with hexagonal handle     | 04060414065305 |
| GF5187 | BAKES bile duct dilator 300mm 12"<br>Ø9.0mm malleable with hexagonal handle     | 04060414065312 |
| GF5189 | BAKES bile duct dilator 300mm 12"<br>Ø10.0mm malleable with hexagonal handle    | 04060414065329 |
| GF5191 | BAKES bile duct dilator 300mm 12"<br>Ø11.0mm malleable with hexagonal handle    | 04060414065336 |
| GF5193 | BAKES bile duct dilator 300mm 12"<br>Ø12.0mm malleable with hexagonal handle    | 04060414065343 |
| GF5195 | BAKES bile duct dilator 300mm 12"<br>Ø13.0mm malleable with hexagonal handle    | 04060414065350 |
| GF5201 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø1.2mm malleable with hexagonal handle | 04060414065367 |
| GF5202 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø1.4mm malleable with hexagonal handle | 04060414065374 |
| GF5203 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø1.6mm malleable with hexagonal handle | 04060414065381 |
| GF5204 | DeBAKEY vascular dilator 190mm 7 1/2"<br>Ø1.8mm malleable with hexagonal handle | 04060414065398 |
| GF5240 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø0.5mm malleable<br>hexagonal handle   | 04060414411942 |
| GF5241 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø1.0mm malleable<br>hexagonal handle   | 04060414411959 |
| GF5242 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø1.5mm malleable<br>hexagonal handle   | 04060414411966 |
| GF5243 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø2.0mm malleable<br>hexagonal handle   | 04060414411973 |
| GF5244 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø2.5mm malleable<br>hexagonal handle   | 04060414411980 |
| GF5245 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø3.0mm malleable<br>hexagonal handle   | 04060414411997 |
| GF5246 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø3.5mm malleable<br>hexagonal handle   | 04060414412000 |
| GF5247 | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø4.0mm malleable<br>hexagonal handle   | 04060414412017 |

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| GF5248  | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø4.5mm malleable<br>hexagonal handle           | 04060414412024 |
| GF5249  | DeBAKEY vascular dilator 140mm 5 1/2"<br>Ø5.0mm malleable<br>hexagonal handle           | 04060414412031 |
| GL0330  | STUECKER gall duct dilator 325mm 13"<br>Ø3.0mm flat tip 4.0mm<br>removable handle       | 04060414070323 |
| GL0340  | STUECKER gall duct dilator 325mm 13"<br>Ø4.0mm flat tip                                 | 04060414070330 |
| GL0350  | Cone set for gall duct dilator<br>Ø9mm Ø11mm and Ø13mm<br>for GL0330 and GL0340         | 04060414070347 |
| GL0360  | Papillotome set consisting of<br>dilator GL0330 and cone set GL0350                     | 04060414070354 |
| GY2960  | Splint guide 180mm 7 1/8"<br>with round handle                                          | 04060414074321 |
| MN1530  | JACOBSON vascular dilator 125mm 5"<br>Ø0.5mm                                            | 04060414114294 |
| MN1530T | JACOBSON vascular dilator 125mm 5"<br>Ø0.5mm titanium                                   | 04060414423716 |
| MN1540  | JACOBSON vascular dilator 125mm 5"<br>Ø1.0mm                                            | 04060414114300 |
| MN1550  | JACOBSON vascular dilator 125mm 5"<br>Ø1.5mm                                            | 04060414114317 |
| MN1560  | BIEMER vessel spreader 160mm 6 1/4"                                                     | 04060414114324 |
| MN1590  | HEIFETZ vessel spreader 100mm 4"                                                        | 04060414114355 |
| MP0050  | Micro vascular dilator 110mm 4 1/4"<br>10° angled round tip 0.3mm<br>with flat handle   | 04060414134940 |
| MP0051  | Micro vascular dilator 110mm 4 1/4"<br>10° angled round tip 0.2mm<br>with flat handle   | 04060414134957 |
| MP0052  | Micro vascular dilator 110mm 4 1/4"<br>10° angled conical tip 0.6mm<br>with flat handle | 04060414134964 |
| MP0053  | Micro vascular dilator 110mm 4 1/4"<br>10° angled conical tip 1.0mm<br>with flat handle | 04060414134971 |
| MP0055  | Micro vascular dilator 110mm 4 1/4"<br>10° angled tip 4x0.3mm<br>with flat handle 9mm   | 04060414134988 |
| MP0055T | Micro vascular dilator 110mm 4 1/4"<br>10° angled tip 4x0.3mm titanium                  | 04060414244885 |

with flat handle 9mm

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| MP0056 | Micro vascular dilator 110mm 4 1/4"<br>10° angled tip 8x0.2mm<br>with flat handle 9mm | 04060414134995 |
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| MP0057 | Micro vascular dilator 110mm 4 1/4"<br>10° angled tip 8x0.1mm<br>with flat handle 9mm | 04060414135008 |
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| MP0058 | Micro vascular dilator 110mm 4 1/4"<br>10° angled tip 8x0.2mm<br>with flat handle 7mm | 04060414135015 |
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| PZ4000 | Vessel dilator 135mm 5 1/4" 45° angled<br>tip 0.3mm | 04060414163742 |
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| PZ4000T | Vessel dilator 135mm 5 1/4" titanium<br>45° angled tip 0.3mm | 04060414244878 |
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| PZ4001T | Vessel dilator 135mm 5 1/4" titanium<br>straight tip 0.3mm | 04060414244892 |
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| TR0580 | Dilatation set<br>from Ø5.5 to Ø10.0mm | 04060414231885 |
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| TR0590 | Dilatation set<br>from Ø5.5 to Ø20.0mm | 04060414231892 |
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| TR0600 | Dilatation set<br>from Ø10.0 to Ø15.0mm | 04060414231908 |
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| TR0610 | Dilatation set<br>from Ø10.0 to Ø20.0mm | 04060414231915 |
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| TR0620 | Dilatation set<br>from Ø10.0 to Ø35.0mm | 04060414231922 |
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| WS0011 | Root probe 200mm 8"<br>Ø4.0mm | 04060414215601 |
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| WS0011-1 | Root probe 195mm 7 3/4"<br>Ø5.0mm | 04060414215618 |
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| \$PA-SOND08 | L070804 | VENOUS STRIPPERS, REUSABLE | 4060414PA-SOND08MH | IR | 6 - 2 |
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| REF    | Name                                                                                          | UDI/GTIN       |
| GF0100 | NABATOFF vein stripping set<br>consisting of plastic scleeve traction<br>rope and metal olive | 04060414050189 |

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| GF0101 | Vein stripper 910mm 36" Ø6.0mm | 04060414050196 |
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| GF0102 | Vein stripper 910mm 36" Ø9.0mm | 04060414050202 |
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| GF0103 | Vein stripper 910mm 36" Ø12.5mm | 04060414050219 |
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| GF0104 | Vein stripper 910mm 36" Ø16.0mm | 04060414050226 |
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| GF0111 | NABATOFF traction rope 900mm only<br>Ø1.3mm for GF0100 | 04060414050240 |
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| GF0112 | NABATOFF filiforme only<br>plastic fine | 04060414050257 |
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for GF0100

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| GF0114 | NABATOFF metal probe tip<br>Ø3.0mm                                                               | 04060414050264 |
| GF0115 | NABATOFF olive only Ø6.0mm                                                                       | 04060414050271 |
| GF0116 | NABATOFF olive only Ø9.0mm                                                                       | 04060414050288 |
| GF0117 | NABATOFF olive only Ø12.0mm                                                                      | 04060414050295 |
| GF0118 | NABATOFF olive only Ø15.0mm                                                                      | 04060414050301 |
| GF0150 | Metal olive only Ø6.0mm                                                                          | 04060414050318 |
| GF0160 | Metal olive only Ø6.0mm                                                                          | 04060414050325 |
| GF0170 | Metal olive only Ø12.0mm                                                                         | 04060414050332 |
| GF0190 | Handle alone for GF0120 and GF0100                                                               | 04060414050356 |
| GF0200 | VARADY mini vein stripping set<br>complete                                                       | 04060414050363 |
| GF0210 | Traction rope 450mm<br>plastic coated                                                            | 04060414050370 |
| GF0220 | VARADY olive only Ø3.0mm                                                                         | 04060414050387 |
| GF0230 | VARADY olive only Ø4.0mm                                                                         | 04060414050394 |
| GF0240 | VARADY olive only Ø5.0mm                                                                         | 04060414050400 |
| GF0250 | Endarterectomy stripper 550mm 22"<br>Ø2.0mm 130° angled without handle                           | 04060414050509 |
| GF0260 | Endarterectomy stripper 550mm 22"<br>Ø3.0mm 130° angled without handle                           | 04060414050516 |
| GF0265 | NOON vascular tunneler 230mm 9 1/8"<br>modified angled with 3 tips<br>6.7 und 9.0mm exchangeable | 04060414050523 |
| GF0270 | Endarterectomy stripper 550mm 22"<br>Ø4.0mm 130° angled without handle                           | 04060414050530 |
| GF0271 | Endarterectomy stripper 550mm 22"<br>Ø6.0mm 130° angled without handle                           | 04060414050547 |
| GF0272 | Endarterectomy stripper 550mm 22"<br>Ø7.0mm 130° angled without handle                           | 04060414050554 |
| GF0273 | Endarterectomy stripper 550mm 22"<br>Ø8.0mm 130° angled without handle                           | 04060414050561 |
| GF0274 | Endarterectomy stripper 550mm 22"<br>Ø10.0mm 130° angled without handle                          | 04060414050578 |
| GF0275 | Endarterectomy stripper 550mm 22"<br>Ø12.0mm 130° angled without handle                          | 04060414050585 |
| GF0276 | Endarterectomy stripper 550mm 22"<br>Ø14.0mm 130° angled without handle                          | 04060414050592 |



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| GF0277 | Handle for endarterectomy stripper<br>GF0250 - GF0276 120mm 4 3/4"                                          | 04060414050608 |
| GF0294 | LEATHER (MILLS) valvulotome 175mm 7"<br>inside sharp 90° angled<br>mirror finish with round handel          | 04060414050615 |
| GF0295 | LEATHER (MILLS) valvulotome 240mm 9 1/2"<br>inside sharp slightly curved<br>mirror finish with round handel | 04060414050622 |
| GF0296 | LEATHER (MILLS) valvulotome 330mm 13"<br>inside sharp slightly curved<br>mirror finish with round handel    | 04060414050639 |
| GF0297 | LEATHER valvulotome 160mm 6 1/4"<br>frontside sharp 80° angled<br>mirror finish with round handel           | 04060414050646 |
| GF0300 | HOFFMANN pin stripper set<br>consisting of 3 pin strippers and<br>and complete olive set                    | 04060414050677 |
| GF0301 | HOFFMANN pin stripper 340mm 13 1/2"<br>curved figure 1                                                      | 04060414050684 |
| GF0302 | HOFFMANN pin stripper 490mm 19 1/2"<br>curved figure 2                                                      | 04060414050691 |
| GF0303 | HOFFMANN pin stripper 590mm 23 1/2"<br>curved figure 3                                                      | 04060414050707 |
| GF0304 | HOFFMANN pin stripper olive only<br>Ø3.5mm with needle eye                                                  | 04060414050714 |
| GF0305 | HOFFMANN pin stripper olive only<br>Ø5.0mm with needle eye                                                  | 04060414050721 |
| KN5710 | REILL tendon stripper<br>Ø3.0mm<br>figure 1                                                                 | 04060414104646 |
| KN5750 | BUNNELL tendon stripper 135mm 5 1/4"<br>Ø3.0mm                                                              | 04060414104660 |
| KN5760 | BUNNELL tendon stripper 135mm 5 1/4"<br>Ø4.0mm                                                              | 04060414104677 |
| KN5770 | BUNNELL tendon stripper 135mm 5 1/4"<br>Ø6.0mm                                                              | 04060414104684 |
| KN5780 | Tendon stripper 300mm 12"<br>with cutter head Ø3.0mm                                                        | 04060414104691 |
| KN5790 | Tendon stripper 300mm 12"<br>with cutter head Ø5.0mm                                                        | 04060414104707 |
| KN5810 | BUNNELL tendon passing probe 230mm<br>9 1/8" straight                                                       | 04060414104721 |
| KN5820 | Tendon passing probe 275mm                                                                                  | 04060414104738 |
| MN2340 | ASSMUS stripper 395mm 15 1/2"<br>Ø3mm working length 350mm blunt                                            | 04060414116151 |

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| \$PA-SOND09 | L031199 | PROBES AND MIRRORS, REUSABLE - OTHER                                                               | 4060414PA-SOND09MK | IR | 6 - 2 |
|             | REF     | Name                                                                                               | UDI/GTIN           |    |       |
|             | AU0100  | Swab holder for for suction strips and suction wedges                                              | 04060414001600     |    |       |
|             | GY2420  | PLAYFAIR cottonapplicator 320mm 12 3/4"                                                            | 04060414073720     |    |       |
|             | HA1640  | HARTMANN postnasal applicator 220mm 8 3/4" rough spiral shaped                                     | 04060414078589     |    |       |
|             | HA3005  | Cotton applicator working length 500mm 20"                                                         | 04060414080551     |    |       |
|             | HA3006  | Cotton applicator working length 350mm 14"                                                         | 04060414080568     |    |       |
|             | OR1320  | FARRELL cotton applicator 110mm 4 1/4" Ø1.2mm round serrated                                       | 04060414154238     |    |       |
|             | OR1330  | "Lathbury-Farrell" cotton applicator Ø 1,4 mm, triangular serrated end 120 mm, 4 1/4" total length | 04060414154269     |    |       |
|             | OR1340  | Applicator slender triangle, "Piccolo" serrated end 110 mm , 4 1/3 " total len diameter 0,7 mm     | 04060414154276     |    |       |
|             | OR1350  | PICCOLO cotton applicator 110mm 4 1/4" Ø0.7mm triangular serrated                                  | 04060414154283     |    |       |
|             | OR1730  | MUSGROVE cerumen needle and cotton applicator 180mm 7 1/8"                                         | 04060414155020     |    |       |
|             | WT0100  | BUCK cotton applicator 120mm 4 3/4" Ø0.9mm                                                         | 04060414217544     |    |       |
|             | WT0128  | Cotton applicator 125mm 5" Ø1.2mm                                                                  | 04060414217575     |    |       |
|             | WT0129  | Cotton applicator 160mm 6 1/4" Ø1.2mm spiral form serration                                        | 04060414217582     |    |       |
|             | WT0130  | Cotton applicator 180mm 7 1/8" Ø1.5mm spiral form serration                                        | 04060414217599     |    |       |
|             | WT0146  | Cotton applicator 120mm 4 3/4" Ø1.5mm spiral form serration                                        | 04060414217612     |    |       |
|             | WT0148  | Cotton applicator 160mm 6 1/4" Ø1.5mm spiral form serration                                        | 04060414217636     |    |       |
|             | WT0149  | Cotton applicator 180mm 7 1/8" Ø1.5mm spiral form serration                                        | 04060414217643     |    |       |
|             | WT0150  | Cotton applicator 180mm 7 1/8" Ø1.8mm                                                              | 04060414217650     |    |       |

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|        | spiral form serration                                                                |                |
| WT0160 | FARRELL cotton applicator 140mm 5 1/2"<br>Ø1.2mm<br>round serrated end               | 04060414217674 |
| WT0170 | FARRELL cotton applicator 180mm 6 1/4"<br>Ø1.2mm<br>spiral form serration            | 04060414217681 |
| WT0180 | LATHBURY-FARRELL cotton applicator 140mm<br>5 1/2" Ø1.4mm<br>triangular serrated end | 04060414217698 |
| WT0190 | LATHBURY-FARRELL cotton applicator 160mm<br>5 1/2" Ø1.2mm<br>triangular serrated end | 04060414217704 |
| WT0199 | Cotton applicator 120mm 4 3/4"<br>Ø0.9mm                                             | 04060414217711 |
| WT0200 | Cotton applicator 135mm 5 1/3"<br>Ø0.9mm                                             | 04060414217728 |
| WT0202 | LATHBURY-FARRELL cotton applicator 180mm<br>7 1/8" Ø1.2mm                            | 04060414217735 |
| WT0210 | LATHBURY-FARRELL cotton applicator 160mm<br>5 1/2" Ø1.4mm<br>triangular serrated end | 04060414217759 |



**PHA-WIDE – Weitende Instrumente**  
**PHA-WIDE – Dilating instruments**

**Annex I zur Konformitätserklärung: Zweckbestimmung**

**Annex I to the declaration of conformity: Intended Purpose**

|                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                   |                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>PA-ACC10</b><br/> Tunnelierungsinstrument, Gefäß:<br/> <i>Vascular tunnelers:</i><br/> Beispiel / example:<br/> <b>GF6037</b></p>                              | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen. Hilfsmittel zur Einführung von<br/> Gefäßprothesen.</p>                                          | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans.<br/> Aids for the introduction of vascular<br/> prostheses.</i></p>                         |
| <p><b>PA-END01</b><br/> Obturator Endoskopie:<br/> <i>Obturator endoscopy:</i><br/> Beispiel / example:<br/> <b>TR3061</b></p>                                       | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen. Schaft zur Verwendung mit<br/> entsprechenden Trokaren oder<br/> Diagnostikschäften.</p>         | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans. Shaft for<br/> use with appropriate trocars or<br/> diagnostic shafts.</i></p>              |
| <p><b>PA-SOND01</b><br/> Sonde Arthroskopie:<br/> <i>Arthroscopy probes:</i><br/> Beispiel / example:<br/> <b>SD0100</b></p>                                         | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen zum Austasten oder<br/> Untersuchen von Hohlräumen in der<br/> allgemeinen Chirurgie.</p>         | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans for probing<br/> or examining cavities in general<br/> surgery.</i></p>                      |
| <p><b>PA-SOND02</b><br/> Fistel Sonden:<br/> <i>Fistula probes:</i><br/> Beispiel / example:<br/> <b>SD0170</b></p>                                                | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen zum Austasten oder<br/> Untersuchen von Fisteln.</p>                                              | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans for<br/> palpation or examination of fistulas</i></p>                                        |
| <p><b>PA-SOND04</b><br/> Gallengangsonden,<br/> Gallensteinlöffel:<br/> <i>Bile duct probes, gallstone spoon:</i><br/> Beispiel / example:<br/> <b>GL0410</b></p>  | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen zum Einführen in den<br/> Gallengang z.B. zum Schaben oder<br/> Ausschaben von Gallensteinen.</p> | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans for<br/> inserting into the bile duct e.g. for<br/> scraping or scraping gallstones.</i></p> |
| <p><b>PA-SOND07</b><br/> Dilatatoren, Gefäß:<br/> <i>Vascular dilators:</i><br/> Beispiel / example:<br/> <b>GL0330</b></p>                                        | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen zum Erweitern von Gefäßen in<br/> der Gefäßchirurgie.</p>                                         | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans for<br/> expanding vessels in vascular surgery.</i></p>                                      |
| <p><b>PA-SOND08</b><br/> Stripper:<br/> <i>Strippers:</i><br/> Beispiel / example:<br/> <b>GF0301</b></p>                                                          | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen zur Entfernung von Varizen<br/> oder Sehnen im Bereich der Extremitäten.</p>                      | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans to remove<br/> varices or tendons in the extremities.</i></p>                                |
| <p><b>PA-SOND09</b><br/> Sonden, sonstige Watteträger:<br/> <i>Tube, others:</i><br/> Beispiel / example:<br/> <b>OR1340</b></p>                                   | <p>Wiederverwendbares chirurgisch<br/> invasives Instrument zur<br/> vorübergehenden Anwendung am<br/> Menschen zum Halten und Applizieren<br/> von Tupfermaterial im OP-Feld.</p>                                | <p><i>Reusable surgical invasive instrument<br/> for transient use on humans for holding<br/> and applying swab material in the<br/> surgical field.</i></p>              |

## Společnost

ASANUS Medizintechnik GmbH  
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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: Rozšiřující nástroje, sondy, dilatátory

**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
- Medizinprodukte-Durchführungsgesetz – 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-ACC10      | L070805 | VASCULAR TUNNELLERS, REUSABLE                                                 | 4060414PA-ACC1034 | IR     | 6 - 2    |
|                 | REF     | Name                                                                          | UDI/GTIN          |        |          |
|                 | GF3920  | Tunnelling forceps 500mm 19 2/3"                                              | 04060414063660    |        |          |
|                 | GF6037  | Tube for tunneling instrument 510mm 20 1/4" slightly curved                   | 04060414065671    |        |          |
|                 | GF6038  | Bulldog mandrin for tunneling instrument 590mm 23 1/2" slightly curved        | 04060414065688    |        |          |
|                 | GF6039  | Tunneling instrument set 590mm 23 1/2" consisting of GF6037 GF6038 and GF6042 | 04060414065695    |        |          |



## PHA-WIDE – Rozšiřující nástroje

### Příloha I k přihlášení o shodě: Určený účel

|                                                                                                                                                                                                                                         |  |                                                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PA-ACC10</b><br>Tunnelierungsinstrument, Gefäß:<br><i>Vascular tunnelers:</i><br>Beispiel / example:<br><b>GF6037</b><br>                           |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí.<br>Pomůcka pro zavádění cévních protéz.                                           |
| <b>PA-END01</b><br>Obturator Endoskopie:<br><i>Obturator endoscopy:</i><br>Beispiel / example:<br><b>TR3061</b><br>                                    |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí. Shafty k použití s vhodnými trokary nebo k diagnostice.                           |
| <b>PA-SOND01</b><br>Sonde Arthroskopie:<br><i>Arthroscopy probes:</i><br>Beispiel / example:<br><b>SD0100</b><br>                                      |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k sondování nebo vyšetřování dutin ve všeob. chirurgii.                            |
| <b>PA-SOND02</b><br>Fistel Sonden:<br><i>Fistula probes:</i><br>Beispiel / example:<br><b>SD0170</b><br>                                             |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k palpaci nebo vyšetření píštělů                                                   |
| <b>PA-SOND04</b><br>Gallengangsonden,<br>Gallensteinspökel:<br><i>Bile duct probes, gallstone spoon:</i><br>Beispiel / example:<br><b>GL0410</b><br> |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k zavedení do žlučového např. kvůli seškrábnutí nebo vyškrábnutí žlučových kamenů. |
| <b>PA-SOND07</b><br>Dilatatoren, Gefäß:<br><i>Vascular dilators:</i><br>Beispiel / example:<br><b>GL0330</b><br>                                     |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k roztažení cév v cévní chirurgii.                                                 |
| <b>PA-SOND08</b><br>Stripper:<br><i>Strippers:</i><br>Beispiel / example:<br><b>GF0301</b><br>                                                       |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k odstranění křečových žil nebo šlach v končetinách.                               |
| <b>PA-SOND09</b><br>Sonden, sonstige Watteträger:<br><i>Tube, others:</i><br>Beispiel / example:<br><b>OR1340</b><br>                                |  | Opakovaně použitelný chirurgický invazivní nástroj ke krátkodobému použití u lidí k přidržení a použití tampónů v operačním poli.                                    |

## 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

**137311/2024-14**

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.

**137311/2024-14**

on **17/06/2024.**

*Mgr. Alice Tejkalová*

Mgr. Alice Tejkalová

