

# Future Knee Modular System

## Product Catalog



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# BIOTECH

REF  
VB-004-PROSP-PC-06-EN-00

Revision  
2  
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CE 1011

## "Movement is Life"

CR - CRUCIATE RETAINING

P/S - POSTERIOR STABILIZED

REVISION



## PRIMARY AND REVISION COMPONENTS - FLEXIBLE INTRAOPERATIVE VARIABILITY



### The Biotech Future Knee- Modular Total Knee System

With the Biotech Future Knee System, there is a wide range of choices of implants that meet the needs of the surgeons, and which provide a high intra operative flexibility, and minimize the restrictions encountered within the conditions of the case study.

Considering these conditions, the Biotech Future Knee System has been designed to provide the solutions for primary, posterior- stabilized and revision indications.

The cemented and uncemented fixations can be easily chosen intra-operatively, and can be implanted with the same set of instruments.

The anatomical design of each component allows the physiological movement to a great extent, thereby overcoming any possible debilitating conditions.

With a total intra-operative flexibility and a single, but accurate set of instruments, a natural joint formation can be developed, and a long life expectancy of the artificial joint can be positively influenced.

#### Important parameters:

- Primary, P/S and revision components can be flexibly combined according to the surgeon's choice during the operation.
- The Modular Titanium Tibial Tray provides a flexible intra-operative choice between primary and revision stems and it can also be extended by Offsets and Tibial Augmentation Blocks if necessary.
- Maximal surface contact of tibial and femoral components to minimize polyethylene wear.
- Anatomical design for best physiological results.



**FUTURE KNEE  
CR Tibial Inserts  
UHMWPE DIN EN ISO 5834-2**



|            |               |
|------------|---------------|
| XXS 8mm *  | 050-4500-0108 |
| XXS 10mm * | 050-4500-0110 |
| XXS 12mm * | 050-4500-0112 |
| XXS 15mm * | 050-4500-0115 |
| XXS 18mm * | 050-4500-0118 |
| XXS 20mm * | 050-4500-0120 |

|         |               |
|---------|---------------|
| XS 8mm  | 050-4500-1108 |
| XS 10mm | 050-4500-1110 |
| XS 12mm | 050-4500-1112 |
| XS 15mm | 050-4500-1115 |
| XS 18mm | 050-4500-1118 |
| XS 20mm | 050-4500-1120 |

|        |               |
|--------|---------------|
| S 8mm  | 050-4500-2108 |
| S 10mm | 050-4500-2110 |
| S 12mm | 050-4500-2112 |
| S 15mm | 050-4500-2115 |
| S 18mm | 050-4500-2118 |
| S 20mm | 050-4500-2120 |

|        |               |
|--------|---------------|
| M 8mm  | 050-4500-3108 |
| M 10mm | 050-4500-3110 |
| M 12mm | 050-4500-3112 |
| M 15mm | 050-4500-3115 |
| M 18mm | 050-4500-3118 |
| M 20mm | 050-4500-3120 |

|        |               |
|--------|---------------|
| L 8mm  | 050-4500-4108 |
| L 10mm | 050-4500-4110 |
| L 12mm | 050-4500-4112 |
| L 15mm | 050-4500-4115 |
| L 18mm | 050-4500-4118 |
| L 20mm | 050-4500-4120 |

|         |               |
|---------|---------------|
| XL 8mm  | 050-4500-5108 |
| XL 10mm | 050-4500-5110 |
| XL 12mm | 050-4500-5112 |
| XL 15mm | 050-4500-5115 |
| XL 18mm | 050-4500-5118 |
| XL 20mm | 050-4500-5120 |

|            |               |
|------------|---------------|
| XXL 8mm *  | 050-4500-6108 |
| XXL 10mm * | 050-4500-6110 |
| XXL 12mm * | 050-4500-6112 |
| XXL 15mm * | 050-4500-6115 |
| XXL 18mm * | 050-4500-6118 |
| XXL 20mm * | 050-4500-6120 |

**FUTURE KNEE  
CR Femoral Components  
CoCr  
DIN EN ISO 5832-4**

Right

|       |               |
|-------|---------------|
| XXS * | 050-1311-0058 |
| XS    | 050-1311-1062 |
| S     | 050-1311-2066 |
| M     | 050-1311-3070 |
| L     | 050-1311-4074 |
| XL    | 050-1311-5078 |
| XXL * | 050-1311-6082 |



Left

|       |               |
|-------|---------------|
| XXS * | 050-1312-0058 |
| XS    | 050-1312-1062 |
| S     | 050-1312-2066 |
| M     | 050-1312-3070 |
| L     | 050-1312-4074 |
| XL    | 050-1312-5078 |
| XXL * | 050-1312-6082 |

**FUTURE KNEE Modular  
Tibial Tray Components  
TiAl6V4 DIN EN ISO 5832-3**

|       |               |
|-------|---------------|
| XXS * | 050-3410-0000 |
| XS    | 050-3410-1000 |
| S     | 050-3410-2000 |
| M     | 050-3410-3000 |
| L     | 050-3410-4000 |
| XL    | 050-3410-5000 |
| XXL * | 050-3410-6000 |



**FUTURE KNEE stem  
for modular tibial tray  
TiAl6V4**

050-5410-0000  
available separately



**FUTURE KNEE  
P/S Tibial Inserts  
UHMWPE DIN EN ISO 5834-2**



|            |               |
|------------|---------------|
| XXS 8mm *  | 056-4500-0208 |
| XXS 10mm * | 056-4500-0210 |
| XXS 12mm * | 056-4500-0212 |
| XXS 15mm * | 056-4500-0215 |
| XXS 18mm * | 056-4500-0218 |
| XXS 20mm * | 056-4500-0220 |

|         |               |
|---------|---------------|
| XS 8mm  | 056-4500-1208 |
| XS 10mm | 056-4500-1210 |
| XS 12mm | 056-4500-1212 |
| XS 15mm | 056-4500-1215 |
| XS 18mm | 056-4500-1218 |
| XS 20mm | 056-4500-1220 |

|        |               |
|--------|---------------|
| S 8mm  | 056-4500-2208 |
| S 10mm | 056-4500-2210 |
| S 12mm | 056-4500-2212 |
| S 15mm | 056-4500-2215 |
| S 18mm | 056-4500-2218 |
| S 20mm | 056-4500-2220 |

|        |               |
|--------|---------------|
| M 8mm  | 056-4500-3208 |
| M 10mm | 056-4500-3210 |
| M 12mm | 056-4500-3212 |
| M 15mm | 056-4500-3215 |
| M 18mm | 056-4500-3218 |
| M 20mm | 056-4500-3220 |

|        |               |
|--------|---------------|
| L 8mm  | 056-4500-4208 |
| L 10mm | 056-4500-4210 |
| L 12mm | 056-4500-4212 |
| L 15mm | 056-4500-4215 |
| L 18mm | 056-4500-4218 |
| L 20mm | 056-4500-4220 |

|         |               |
|---------|---------------|
| XL 8mm  | 056-4500-5208 |
| XL 10mm | 056-4500-5210 |
| XL 12mm | 056-4500-5212 |
| XL 15mm | 056-4500-5215 |
| XL 18mm | 056-4500-5218 |
| XL 20mm | 056-4500-5220 |

|            |               |
|------------|---------------|
| XXL 8mm *  | 056-4500-6208 |
| XXL 10mm * | 056-4500-6210 |
| XXL 12mm * | 056-4500-6212 |
| XXL 15mm * | 056-4500-6215 |
| XXL 18mm * | 056-4500-6218 |
| XXL 20mm * | 056-4500-6220 |

**FUTURE KNEE  
P/S Femoral  
Components - CoCr  
DIN EN ISO 5832-4**

Right

|       |               |
|-------|---------------|
| XXS * | 056-1311-0258 |
| XS    | 056-1311-1262 |
| S     | 056-1311-2266 |
| M     | 056-1311-3270 |
| L     | 056-1311-4274 |
| XL    | 056-1311-5278 |
| XXL * | 056-1311-6282 |



Left

|       |               |
|-------|---------------|
| XXS * | 056-1312-0258 |
| XS    | 056-1312-1262 |
| S     | 056-1312-2266 |
| M     | 056-1312-3270 |
| L     | 056-1312-4274 |
| XL    | 056-1312-5278 |
| XXL * | 056-1312-6282 |



**Patella Components  
UHMWPE  
DIN EN ISO 5834-2**

|   |               |
|---|---------------|
| S | 051-7110-0332 |
| M | 051-7110-0334 |
| L | 051-7110-0337 |

\* - optional

**"Movement is Life"**



**Future Knee Cemented Revision  
femoral components  
CoCr DIN EN ISO 5832-4**

**Right**

|       |               |
|-------|---------------|
| XXS * | 065-1311-0558 |
| XS    | 065-1311-1562 |
| S     | 065-1311-2566 |
| M     | 065-1311-3570 |
| L     | 065-1311-4574 |
| XL    | 065-1311-5578 |
| XXL * | 065-1311-6582 |

**Left**

|       |               |
|-------|---------------|
| XXS * | 065-1312-0558 |
| XS    | 065-1312-1562 |
| S     | 065-1312-2566 |
| M     | 065-1312-3570 |
| L     | 065-1312-4574 |
| XL    | 065-1312-5578 |
| XXL * | 065-1312-6582 |

**Future Knee Revision  
Universal Cemented Stems  
TiAl6V4 DIN EN ISO 5832-3**

|          |               |
|----------|---------------|
| 10x50 *  | 065-5410-0510 |
| 10x80 *  | 065-5410-0810 |
| 10x110 * | 065-5410-1110 |
| 10x140 * | 065-5410-1410 |
| 10x170 * | 065-5410-1710 |
| 12x50 *  | 065-5410-0512 |
| 12x80    | 065-5410-0812 |
| 12x110   | 065-5410-1112 |
| 12x140   | 065-5410-1412 |
| 12x170 * | 065-5410-1712 |
| 14x50 *  | 065-5410-0514 |
| 14x80    | 065-5410-0814 |
| 14x110   | 065-5410-1114 |
| 14x140   | 065-5410-1414 |
| 14x170 * | 065-5410-1714 |
| 16x50 *  | 065-5410-0516 |
| 16x80    | 065-5410-0816 |
| 16x110   | 065-5410-1116 |
| 16x140   | 065-5410-1416 |
| 16x170 * | 065-5410-1716 |
| 18x50 *  | 065-5410-0518 |
| 18x80 *  | 065-5410-0818 |
| 18x110 * | 065-5410-1118 |
| 18x140 * | 065-5410-1418 |
| 18x170 * | 065-5410-1718 |

**Future Knee Revision Stem adapters  
TiAl6V4 DIN EN ISO 5832-3**

|                                            |               |
|--------------------------------------------|---------------|
| Adapter for Revision Universal Stem 5°, 9° | 065-9415-0001 |
| Adapter for Revision Universal Stem 7°     | 065-9415-0002 |

**Future Knee Revision Stem offsets  
TiAl6V4 DIN EN ISO 5832-3**

|                                          |     |               |
|------------------------------------------|-----|---------------|
| Long offset for Tibial Stem Offset       | 3mm | 065-1415-0500 |
| Short offset for Femoral and Tibial Stem | 3mm | 065-2415-0500 |
| Long offset for Tibial Stem Offset       | 6mm | 065-3415-0500 |
| Short offset for Femoral and Tibial Stem | 6mm | 065-4415-0500 |

**Future Knee Revision  
Tibial Inserts  
UHMWPE DIN EN ISO 5834-2**

|            |               |
|------------|---------------|
| XXS 8mm *  | 065-4500-0508 |
| XXS 10mm * | 065-4500-0510 |
| XXS 12mm * | 065-4500-0512 |
| XXS 15mm * | 065-4500-0515 |
| XXS 18mm * | 065-4500-0518 |
| XXS 20mm * | 065-4500-0520 |
| XS 8mm     | 065-4500-1508 |
| XS 10mm    | 065-4500-1510 |
| XS 12mm    | 065-4500-1512 |
| XS 15mm    | 065-4500-1515 |
| XS 18mm    | 065-4500-1518 |
| XS 20mm    | 065-4500-1520 |
| S 8mm      | 065-4500-2508 |
| S 10mm     | 065-4500-2510 |
| S 12mm     | 065-4500-2512 |
| S 15mm     | 065-4500-2515 |
| S 18mm     | 065-4500-2518 |
| S 20mm     | 065-4500-2520 |
| M 8mm      | 065-4500-3508 |
| M 10mm     | 065-4500-3510 |
| M 12mm     | 065-4500-3512 |
| M 15mm     | 065-4500-3515 |
| M 18mm     | 065-4500-3518 |
| M 20mm     | 065-4500-3520 |
| L 8mm      | 065-4500-4508 |
| L 10mm     | 065-4500-4510 |
| L 12mm     | 065-4500-4512 |
| L 15mm     | 065-4500-4515 |
| L 18mm     | 065-4500-4518 |
| L 20mm     | 065-4500-4520 |
| XL 8mm     | 065-4500-5508 |
| XL 10mm    | 065-4500-5510 |
| XL 12mm    | 065-4500-5512 |
| XL 15mm    | 065-4500-5515 |
| XL 18mm    | 065-4500-5518 |
| XL 20mm    | 065-4500-5520 |
| XXL 8mm *  | 065-4500-6508 |
| XXL 10mm * | 065-4500-6510 |
| XXL 12mm * | 065-4500-6512 |
| XXL 15mm * | 065-4500-6515 |
| XXL 18mm * | 065-4500-6518 |
| XXL 20mm * | 065-4500-6520 |

**Future Knee FAB  
TiAl6V4 DIN EN ISO 5832-3**

**4mm**

|                        |               |
|------------------------|---------------|
| XXS 4mm LM/RL DISTAL * | 065-0403-0004 |
| XXS 4mm LL/RM DISTAL * | 065-0400-0204 |
| XXS 4mm POSTERIOR *    | 065-0404-1104 |
| XS 4mm LM/RL DISTAL    | 065-0403-1004 |
| XS 4mm LL/RM DISTAL    | 065-0400-1204 |
| XS 4mm POSTERIOR       | 065-0404-2104 |
| S 4mm LM/RL DISTAL     | 065-0403-2004 |
| S 4mm LL/RM DISTAL     | 065-0400-2204 |
| S 4mm POSTERIOR        | 065-0404-3104 |
| M 4mm LM/RL DISTAL     | 065-0403-3004 |
| M 4mm LL/RM DISTAL     | 065-0400-3204 |
| M 4mm POSTERIOR        | 065-0404-4104 |
| L 4mm LM/RL DISTAL     | 065-0403-4004 |
| L 4mm LL/RM DISTAL     | 065-0400-4204 |
| L 4mm POSTERIOR        | 065-0404-5104 |
| XL 4mm LM/RL DISTAL    | 065-0403-5004 |
| XL 4mm LL/RM DISTAL    | 065-0400-5204 |
| XL 4mm POSTERIOR       | 065-0404-6104 |
| XXL 4mm LM/RL DISTAL * | 065-0403-6004 |
| XXL 4mm LL/RM DISTAL * | 065-0400-6204 |
| XXL 4mm POSTERIOR *    | 065-0404-7104 |

**8mm**

|                        |               |
|------------------------|---------------|
| XXS 8mm LM/RL DISTAL * | 065-0403-0008 |
| XXS 8mm LL/RM DISTAL * | 065-0400-0208 |
| XXS 8mm POSTERIOR *    | 065-0404-1108 |
| XS 8mm LM/RL DISTAL    | 065-0403-1008 |
| XS 8mm LL/RM DISTAL    | 065-0400-1208 |
| XS 8mm POSTERIOR       | 065-0404-2108 |
| S 8mm LM/RL DISTAL     | 065-0403-2008 |
| S 8mm LL/RM DISTAL     | 065-0400-2208 |
| S 8mm POSTERIOR        | 065-0404-3108 |
| M 8mm LM/RL DISTAL     | 065-0403-3008 |
| M 8mm LL/RM DISTAL     | 065-0400-3208 |
| M 8mm POSTERIOR        | 065-0404-4108 |
| L 8mm LM/RL DISTAL     | 065-0403-4008 |
| L 8mm LL/RM DISTAL     | 065-0400-4208 |
| L 8mm POSTERIOR        | 065-0404-5108 |
| XL 8mm LM/RL DISTAL    | 065-0403-5008 |
| XL 8mm LL/RM DISTAL    | 065-0400-5208 |
| XL 8mm POSTERIOR       | 065-0404-6108 |
| XXL 8mm LM/RL DISTAL * | 065-0403-6008 |
| XXL 8mm LL/RM DISTAL * | 065-0400-6208 |
| XXL 8mm POSTERIOR *    | 065-0404-7108 |

**Future Knee FAB  
TiAl6V4 DIN EN ISO 5832-3**

**12mm**

|                         |               |
|-------------------------|---------------|
| XXS 12mm LM/RL DISTAL * | 065-0403-0012 |
| XXS 12mm LL/RM DISTAL * | 065-0400-0212 |
| XXS 12mm POSTERIOR *    | 065-0404-1112 |
| XS 12mm LM/RL DISTAL    | 065-0403-1012 |
| XS 12mm LL/RM DISTAL    | 065-0400-1212 |
| XS 12mm POSTERIOR       | 065-0404-2112 |
| S 12mm LM/RL DISTAL     | 065-0403-2012 |
| S 12mm LL/RM DISTAL     | 065-0400-2212 |
| S 12mm POSTERIOR        | 065-0404-3112 |
| M 12mm LM/RL DISTAL     | 065-0403-3012 |
| M 12mm LL/RM DISTAL     | 065-0400-3212 |
| M 12mm POSTERIOR        | 065-0404-4112 |
| L 12mm LM/RL DISTAL     | 065-0403-4012 |
| L 12mm LL/RM DISTAL     | 065-0400-4212 |
| L 12mm POSTERIOR        | 065-0404-5112 |
| XL 12mm LM/RL DISTAL    | 065-0403-5012 |
| XL 12mm LL/RM DISTAL    | 065-0400-5212 |
| XL 12mm POSTERIOR       | 065-0404-6112 |
| XXL 12mm LM/RL DISTAL * | 065-0403-6012 |
| XXL 12mm LL/RM DISTAL * | 065-0400-6212 |
| XXL 12mm POSTERIOR *    | 065-0404-7112 |

**Future Knee TAB  
TiAl6V4 DIN EN ISO 5832-3**

|           |               |
|-----------|---------------|
| XXS 6mm * | 065-8400-0006 |
| XS 6mm    | 065-8400-1006 |
| S 6mm     | 065-8400-2006 |
| M 6mm     | 065-8400-3006 |
| L 6mm     | 065-8400-4006 |
| XL 6mm    | 065-8400-5006 |
| XXL 6mm * | 065-8400-6006 |

|           |               |
|-----------|---------------|
| XXS 9mm * | 065-8400-0009 |
| XS 9mm    | 065-8400-1009 |
| S 9mm     | 065-8400-2009 |
| M 9mm     | 065-8400-3009 |
| L 9mm     | 065-8400-4009 |
| XL 9mm    | 065-8400-5009 |
| XXL 9mm * | 065-8400-6009 |

|            |               |
|------------|---------------|
| XXS 12mm * | 065-8400-0012 |
| XS 12mm    | 065-8400-1012 |
| S 12mm     | 065-8400-2012 |
| M 12mm     | 065-8400-3012 |
| L 12mm     | 065-8400-4012 |
| XL 12mm    | 065-8400-5012 |
| XXL 12mm * | 065-8400-6012 |

|            |               |
|------------|---------------|
| XXS 15mm * | 065-8400-0015 |
| XS 15mm    | 065-8400-1015 |
| S 15mm     | 065-8400-2015 |
| M 15mm     | 065-8400-3015 |
| L 15mm     | 065-8400-4015 |
| XL 15mm    | 065-8400-5015 |
| XXL 15mm * | 065-8400-6015 |

|            |               |
|------------|---------------|
| XXS 18mm * | 065-8400-0018 |
| XS 18mm    | 065-8400-1018 |
| S 18mm     | 065-8400-2018 |
| M 18mm     | 065-8400-3018 |
| L 18mm     | 065-8400-4018 |
| XL 18mm    | 065-8400-5018 |
| XXL 18mm * | 065-8400-6018 |

\* - optional



# Future Knee 1 System

## Product Catalog



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# BIOTECH

REF  
VB-004-PROSP-PC-06-EN-00

Revision  
2

Publication date :  
01.04.2022.

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## "Movement is Life"





## THE TOTAL KNEE SYSTEM

In the Biotech FUTURE KNEE 1 System, there is a wide range of choice of implants meeting the needs of surgeons, which provide a high intraoperative flexibility and minimize the restrictions, defined in the system condition of the case study.

According to these, the Biotech FUTURE KNEE 1 System have been designed to provide solutions for Primary, Posterior-Stabilized and Revision indications. The cemented and the uncemented fixation can be flexibly chosen in given intraoperative situations, and can be made with the same set of instruments.

The anatomical design of each component allows physiological movements in great extent, overcoming the arising destructive conditions. With total intraoperative flexibility and single, but accurate set of instruments, a natural joint formation can be developed and a long-life expectancy of the artificial joint can be influenced positively.

## Important parameters:

- Anatomical CoCr femoral components
- optional: also available in uncemented version
- CoCr Tibial Tray to minimize polyethylene wear, one piece and modular
- optional: also available in uncemented version and "All Poly" tibia
- Primary Tibial Insert lipped
- P/S Femoral components
- P/S Tibial Insert
- Meniscal bearing components
- Insert screw fixation to reduce micro motion between the insert and the tibial tray
- Revision CoCr femoral components
- Different stem lengths to increase the joint stability in revision components
- Femoral and Tibial Augmentation Block
- Flexible angular fit (5°, 7°, 9°) of the femoral stems for revision components
- Maximal surface contact of tibial and femoral components to minimize polyethylene wear



**Order information:****FUTURE KNEE 1 Femoral Components - CoCr  
DIN EN ISO 5832-4**

|       |               |
|-------|---------------|
| Right |               |
| XXS * | 058-1311-0058 |
| XS    | 058-1311-1062 |
| S     | 058-1311-2066 |
| M     | 058-1311-3070 |
| L     | 058-1311-4074 |
| XL    | 058-1311-5078 |
| XXL * | 058-1311-6082 |
| Left  |               |
| XXS * | 058-1312-0058 |
| XS    | 058-1312-1062 |
| S     | 058-1312-2066 |
| M     | 058-1312-3070 |
| L     | 058-1312-4074 |
| XL    | 058-1312-5078 |
| XXL * | 058-1312-6082 |

**FUTURE KNEE 1 Tibial Inserts  
UHMWPE DIN EN ISO 5834-2**

|            |               |
|------------|---------------|
| XXS 8mm *  | 058-4500-0108 |
| XXS 10mm * | 058-4500-0110 |
| XXS 12mm * | 058-4500-0112 |
| XXS 15mm * | 058-4500-0115 |
| XXS 18mm * | 058-4500-0118 |
| XXS 20mm * | 058-4500-0120 |
| XS 8mm     | 058-4500-1108 |
| XS 10mm    | 058-4500-1110 |
| XS 12mm    | 058-4500-1112 |
| XS 15mm    | 058-4500-1115 |
| XS 18mm    | 058-4500-1118 |
| XS 20mm    | 058-4500-1120 |
| S 8mm      | 058-4500-2108 |
| S 10mm     | 058-4500-2110 |
| S 12mm     | 058-4500-2112 |
| S 15mm     | 058-4500-2115 |
| S 18mm     | 058-4500-2118 |
| S 20mm     | 058-4500-2120 |
| M 8mm      | 058-4500-3108 |
| M 10mm     | 058-4500-3110 |
| M 12mm     | 058-4500-3112 |
| M 15mm     | 058-4500-3115 |
| M 18mm     | 058-4500-3118 |
| M 20mm     | 058-4500-3120 |
| L 8mm      | 058-4500-4108 |
| L 10mm     | 058-4500-4110 |
| L 12mm     | 058-4500-4112 |
| L 15mm     | 058-4500-4115 |
| L 18mm     | 058-4500-4118 |
| L 20mm     | 058-4500-4120 |
| XL 8mm     | 058-4500-5108 |
| XL 10mm    | 058-4500-5110 |
| XL 12mm    | 058-4500-5112 |
| XL 15mm    | 058-4500-5115 |
| XL 18mm    | 058-4500-5118 |
| XL 20mm    | 058-4500-5120 |
| XXL 8mm *  | 058-4500-6108 |
| XXL 10mm * | 058-4500-6110 |
| XXL 12mm * | 058-4500-6112 |
| XXL 15mm * | 058-4500-6115 |
| XXL 18mm * | 058-4500-6118 |
| XXL 20mm * | 058-4500-6120 |

**FUTURE KNEE 1 One Piece  
Tibial Tray Components  
CoCr DIN EN ISO 5832-4**

|       |               |
|-------|---------------|
| XXS * | 058-3410-0000 |
| XS    | 058-3410-1000 |
| S     | 058-3410-2000 |
| M     | 058-3410-3000 |
| L     | 058-3410-4000 |
| XL    | 058-3410-5000 |
| XXL * | 058-3410-6000 |

\* - optional

**FUTURE KNEE 1 P/S Femoral  
Components - CoCr  
DIN EN ISO 5832-4**

|       |               |
|-------|---------------|
| Right |               |
| XXS * | 059-1311-0258 |
| XS    | 059-1311-1262 |
| S     | 059-1311-2266 |
| M     | 059-1311-3272 |
| L     | 059-1311-4274 |
| XL    | 059-1311-5278 |
| XXL * | 059-1311-6282 |

|       |               |
|-------|---------------|
| Left  |               |
| XXS * | 059-1312-0258 |
| XS    | 059-1312-1262 |
| S     | 059-1312-2266 |
| M     | 059-1312-3272 |
| L     | 059-1312-4274 |
| XL    | 059-1312-5278 |
| XXL * | 059-1312-6282 |

**FUTURE KNEE 1 P/S Tibial Inserts  
UHMWPE DIN EN ISO 5834-2**

|            |               |
|------------|---------------|
| XXS 8mm *  | 059-4500-0208 |
| XXS 10mm * | 059-4500-0210 |
| XXS 12mm * | 059-4500-0212 |
| XXS 15mm * | 059-4500-0215 |
| XXS 18mm * | 059-4500-0218 |
| XXS 20mm * | 059-4500-0220 |
| XS 8mm     | 059-4500-1208 |
| XS 10mm    | 059-4500-1210 |
| XS 12mm    | 059-4500-1212 |
| XS 15mm    | 059-4500-1215 |
| XS 18mm    | 059-4500-1218 |
| XS 20mm    | 059-4500-1220 |
| S 8mm      | 059-4500-2208 |
| S 10mm     | 059-4500-2210 |
| S 12mm     | 059-4500-2212 |
| S 15mm     | 059-4500-2215 |
| S 18mm     | 059-4500-2218 |
| S 20mm     | 059-4500-2220 |
| M 8mm      | 059-4500-3208 |
| M 10mm     | 059-4500-3210 |
| M 12mm     | 059-4500-3212 |
| M 15mm     | 059-4500-3215 |
| M 18mm     | 059-4500-3218 |
| M 20mm     | 059-4500-3220 |
| L 8mm      | 059-4500-4208 |
| L 10mm     | 059-4500-4210 |
| L 12mm     | 059-4500-4212 |
| L 15mm     | 059-4500-4215 |
| L 18mm     | 059-4500-4218 |
| L 20mm     | 059-4500-4220 |
| XL 8mm     | 059-4500-5208 |
| XL 10mm    | 059-4500-5210 |
| XL 12mm    | 059-4500-5212 |
| XL 15mm    | 059-4500-5215 |
| XL 18mm    | 059-4500-5218 |
| XL 20mm    | 059-4500-5220 |
| XXL 8mm *  | 059-4500-6208 |
| XXL 10mm * | 059-4500-6210 |
| XXL 12mm * | 059-4500-6212 |
| XXL 15mm * | 059-4500-6215 |
| XXL 18mm * | 059-4500-6218 |
| XXL 20mm * | 059-4500-6220 |

**Patella Components  
UHMWPE DIN EN ISO 5834-2**

|   |               |
|---|---------------|
| S | 051-7110-0332 |
| M | 051-7110-0334 |
| L | 051-7110-0337 |

**FUTURE KNEE 1 CR Meniscal Bearing  
Tibial Insert - Cruciate Retaining  
UHMWPE DIN EN ISO 5834-2**

|              |               |
|--------------|---------------|
| XX-S 8 mm *  | 063-4501-0208 |
| XX-S 10 mm * | 063-4501-0210 |
| XX-S 12 mm * | 063-4501-0212 |
| XX-S 15 mm * | 063-4501-0215 |
| XX-S 18 mm * | 063-4501-0218 |
| XX-S 20 mm * | 063-4501-0220 |
| X-S 8 mm     | 063-4501-1208 |
| X-S 10 mm    | 063-4501-1210 |
| X-S 12 mm    | 063-4501-1212 |
| X-S 15 mm    | 063-4501-1215 |
| X-S 18 mm    | 063-4501-1218 |
| X-S 20 mm    | 063-4501-1220 |
| S 8 mm       | 063-4501-2208 |
| S 10 mm      | 063-4501-2210 |
| S 12 mm      | 063-4501-2212 |
| S 15 mm      | 063-4501-2215 |
| S 18 mm      | 063-4501-2218 |
| S 20 mm      | 063-4501-2220 |
| M 8 mm       | 063-4501-3208 |
| M 10 mm      | 063-4501-3210 |
| M 12 mm      | 063-4501-3212 |
| M 15 mm      | 063-4501-3215 |
| M 18 mm      | 063-4501-3218 |
| M 20 mm      | 063-4501-3220 |
| L 8 mm       | 063-4501-4208 |
| L 10 mm      | 063-4501-4210 |
| L 12 mm      | 063-4501-4212 |
| L 15 mm      | 063-4501-4215 |
| L 18 mm      | 063-4501-4218 |
| L 20 mm      | 063-4501-4220 |
| X-L 8 mm     | 063-4501-5208 |
| X-L 10 mm    | 063-4501-5210 |
| X-L 12 mm    | 063-4501-5212 |
| X-L 15 mm    | 063-4501-5215 |
| X-L 18 mm    | 063-4501-5218 |
| X-L 20 mm    | 063-4501-5220 |
| XX-L 8 mm *  | 063-4501-6208 |
| XX-L 10 mm * | 063-4501-6210 |
| XX-L 12 mm * | 063-4501-6212 |
| XX-L 15 mm * | 063-4501-6215 |
| XX-L 18 mm * | 063-4501-6218 |
| XX-L 20 mm * | 063-4501-6220 |

**FUTURE KNEE 1 P/S Meniscal Bearing  
Tibial Inserts  
UHMWPE DIN EN ISO 5834-2**

|            |               |
|------------|---------------|
| XXS 8mm *  | 063-4500-0208 |
| XXS 10mm * | 063-4500-0210 |
| XXS 12mm * | 063-4500-0212 |
| XXS 15mm * | 063-4500-0215 |
| XXS 18mm * | 063-4500-0218 |
| XXS 20mm * | 063-4500-0220 |
| XS 8mm     | 063-4500-1208 |
| XS 10mm    | 063-4500-1210 |
| XS 12mm    | 063-4500-1212 |
| XS 15mm    | 063-4500-1215 |
| XS 18mm    | 063-4500-1218 |
| XS 20mm    | 063-4500-1220 |
| S 8mm      | 063-4500-2208 |
| S 10mm     | 063-4500-2210 |
| S 12mm     | 063-4500-2212 |
| S 15mm     | 063-4500-2215 |
| S 18mm     | 063-4500-2218 |
| S 20mm     | 063-4500-2220 |
| M 8mm      | 063-4500-3208 |
| M 10mm     | 063-4500-3210 |
| M 12mm     | 063-4500-3212 |
| M 15mm     | 063-4500-3215 |
| M 18mm     | 063-4500-3218 |
| M 20mm     | 063-4500-3220 |
| L 8mm      | 063-4500-4208 |
| L 10mm     | 063-4500-4210 |
| L 12mm     | 063-4500-4212 |
| L 15mm     | 063-4500-4215 |
| L 18mm     | 063-4500-4218 |
| L 20mm     | 063-4500-4220 |
| XL 8mm     | 063-4500-5208 |
| XL 10mm    | 063-4500-5210 |
| XL 12mm    | 063-4500-5212 |
| XL 15mm    | 063-4500-5215 |
| XL 18mm    | 063-4500-5218 |
| XL 20mm    | 063-4500-5220 |
| XXL 8mm *  | 063-4500-6208 |
| XXL 10mm * | 063-4500-6210 |
| XXL 12mm * | 063-4500-6212 |
| XXL 15mm * | 063-4500-6215 |
| XXL 18mm * | 063-4500-6218 |
| XXL 20mm * | 063-4500-6220 |

**FUTURE KNEE 1  
Meniscal Bearing  
Tibial Tray Components  
CoCr DIN EN ISO 5832-4**

|       |               |
|-------|---------------|
| XXS * | 063-3410-0000 |
| XS    | 063-3410-1000 |
| S     | 063-3410-2000 |
| M     | 063-3410-3000 |
| L     | 063-3410-4000 |
| XL    | 063-3410-5000 |
| XXL * | 063-3410-6000 |

# "Movement is Life"



**TRK Revision Cemented Femoral Components**  
**CoCr DIN EN ISO 5832-4**

**Right**

|       |               |
|-------|---------------|
| XXS * | 054-1311-0558 |
| XS    | 054-1311-1562 |
| S     | 054-1311-2566 |
| M     | 054-1311-3570 |
| L     | 054-1311-4574 |
| XL    | 054-1311-5578 |
| XXL * | 054-1311-6582 |

**Left**

|       |               |
|-------|---------------|
| XXS * | 054-1312-0558 |
| XS    | 054-1312-1562 |
| S     | 054-1312-2566 |
| M     | 054-1312-3570 |
| L     | 054-1312-4574 |
| XL    | 054-1312-5578 |
| XXL * | 054-1312-6582 |

**TRK Revision Cemented Universal Stems**  
**TiAl6V4 DIN EN ISO 5832-3**

|          |               |
|----------|---------------|
| 10x50 *  | 054-5410-0510 |
| 10x80 *  | 054-5410-0810 |
| 10x110 * | 054-5410-1110 |
| 10x140 * | 054-5410-1410 |
| 10x170 * | 054-5410-1710 |
| 12x50 *  | 054-5410-0512 |
| 12x80    | 054-5410-0812 |
| 12x110   | 054-5410-1112 |
| 12x140   | 054-5410-1412 |
| 12x170 * | 054-5410-1712 |
| 14x50 *  | 054-5410-0514 |
| 14x80    | 054-5410-0814 |
| 14x110   | 054-5410-1114 |
| 14x140   | 054-5410-1414 |
| 14x170 * | 054-5410-1714 |
| 16x50 *  | 054-5410-0516 |
| 16x80    | 054-5410-0816 |
| 16x110   | 054-5410-1116 |
| 16x140   | 054-5410-1416 |
| 16x170 * | 054-5410-1716 |
| 18x50 *  | 054-5410-0518 |
| 18x80 *  | 054-5410-0818 |
| 18x110 * | 054-5410-1118 |
| 18x140 * | 054-5410-1418 |
| 18x170 * | 054-5410-1718 |

**TRK Revision Stem Adapters**  
**TiAl6V4 DIN EN ISO 5832-3**

Adapter for Revision Universal Stem 5°, 9°  
Adapter for Revision Universal Stem 7°

054-9415-0001  
054-9415-0002

**TRK Revision Stem Offsets**  
**TiAl6V4 DIN EN ISO 5832-3**

Long offset for Tibial Stem Offset  
Short offset for Femoral and Tibial Stem  
Long offset for Tibial Stem Offset  
Short offset for Femoral and Tibial Stem

3mm 054-1415-0500  
3mm 054-2415-0500  
6mm 054-3415-0500  
6mm 054-4415-0500

**TRK Revision Tibial Inserts**  
**UHMWPE DIN EN ISO 5834-2**

|            |               |
|------------|---------------|
| XXS 8mm *  | 054-4500-0508 |
| XXS 10mm * | 054-4500-0510 |
| XXS 12mm * | 054-4500-0512 |
| XXS 15mm * | 054-4500-0515 |
| XXS 18mm * | 054-4500-0518 |
| XXS 20mm * | 054-4500-0520 |
| XS 8mm     | 054-4500-1508 |
| XS 10mm    | 054-4500-1510 |
| XS 12mm    | 054-4500-1512 |
| XS 15mm    | 054-4500-1515 |
| XS 18mm    | 054-4500-1518 |
| XS 20mm    | 054-4500-1520 |
| S 8mm      | 054-4500-2508 |
| S 10mm     | 054-4500-2510 |
| S 12mm     | 054-4500-2512 |
| S 15mm     | 054-4500-2515 |
| S 18mm     | 054-4500-2518 |
| S 20mm     | 054-4500-2520 |
| M 8mm      | 054-4500-3508 |
| M 10mm     | 054-4500-3510 |
| M 12mm     | 054-4500-3512 |
| M 15mm     | 054-4500-3515 |
| M 18mm     | 054-4500-3518 |
| M 20mm     | 054-4500-3520 |
| L 8mm      | 054-4500-4508 |
| L 10mm     | 054-4500-4510 |
| L 12mm     | 054-4500-4512 |
| L 15mm     | 054-4500-4515 |
| L 18mm     | 054-4500-4518 |
| L 20mm     | 054-4500-4520 |
| XL 8mm     | 054-4500-5508 |
| XL 10mm    | 054-4500-5510 |
| XL 12mm    | 054-4500-5512 |
| XL 15mm    | 054-4500-5515 |
| XL 18mm    | 054-4500-5518 |
| XL 20mm    | 054-4500-5520 |
| XXL 8mm *  | 054-4500-6508 |
| XXL 10mm * | 054-4500-6510 |
| XXL 12mm * | 054-4500-6512 |
| XXL 15mm * | 054-4500-6515 |
| XXL 18mm * | 054-4500-6518 |
| XXL 20mm * | 054-4500-6520 |

**TRK Revision Tibial Tray**  
**TiAl6V4 DIN EN ISO 5832-3**

|       |               |
|-------|---------------|
| XXS * | 054-3410-0500 |
| XS    | 054-3410-1500 |
| S     | 054-3410-2500 |
| M     | 054-3410-3500 |
| L     | 054-3410-4500 |
| XL    | 054-3410-5500 |
| XXL * | 054-3410-6500 |

**TRK Revision TAB**  
**TiAl6V4 DIN EN ISO 5832-3**

|           |               |
|-----------|---------------|
| XXS 6mm * | 054-8400-0006 |
| XS 6mm    | 054-8400-1006 |
| S 6mm     | 054-8400-2006 |
| M 6mm     | 054-8400-3006 |
| L 6mm     | 054-8400-4006 |
| XL 6mm    | 054-8400-5006 |
| XXL 6mm * | 054-8400-6006 |

|           |               |
|-----------|---------------|
| XXS 9mm * | 054-8400-0009 |
| XS 9mm    | 054-8400-1009 |
| S 9mm     | 054-8400-2009 |
| M 9mm     | 054-8400-3009 |
| L 9mm     | 054-8400-4009 |
| XL 9mm    | 054-8400-5009 |
| XXL 9mm * | 054-8400-6009 |

|            |               |
|------------|---------------|
| XXS 12mm * | 054-8400-0012 |
| XS 12mm    | 054-8400-1012 |
| S 12mm     | 054-8400-2012 |
| M 12mm     | 054-8400-3012 |
| L 12mm     | 054-8400-4012 |
| XL 12mm    | 054-8400-5012 |
| XXL 12mm * | 054-8400-6012 |

|            |               |
|------------|---------------|
| XXS 15mm * | 054-8400-0015 |
| XS 15mm    | 054-8400-1015 |
| S 15mm     | 054-8400-2015 |
| M 15mm     | 054-8400-3015 |
| L 15mm     | 054-8400-4015 |
| XL 15mm    | 054-8400-5015 |
| XXL 15mm * | 054-8400-6015 |

|            |               |
|------------|---------------|
| XXS 18mm * | 054-8400-0018 |
| XS 18mm    | 054-8400-1018 |
| S 18mm     | 054-8400-2018 |
| M 18mm     | 054-8400-3018 |
| L 18mm     | 054-8400-4018 |
| XL 18mm    | 054-8400-5018 |
| XXL 18mm * | 054-8400-6018 |

\* - optional

**TRK Revision FAB**  
**TiAl6V4 DIN EN ISO 5832-3**

|                        |               |
|------------------------|---------------|
| <b>4mm</b>             |               |
| XXS 4mm LM/RL DISTAL * | 054-0403-0004 |
| XXS 4mm LL/RM DISTAL * | 054-0400-0204 |
| XXS 4mm POSTERIOR *    | 054-0404-1104 |
| XS 4mm LM/RL DISTAL    | 054-0403-1004 |
| XS 4mm LL/RM DISTAL    | 054-0400-1204 |
| XS 4mm POSTERIOR       | 054-0404-2104 |
| S 4mm LM/RL DISTAL     | 054-0403-2004 |
| S 4mm LL/RM DISTAL     | 054-0400-2204 |
| S 4mm POSTERIOR        | 054-0404-3104 |
| M 4mm LM/RL DISTAL     | 054-0403-3004 |
| M 4mm LL/RM DISTAL     | 054-0400-3204 |
| M 4mm POSTERIOR        | 054-0404-4104 |
| L 4mm LM/RL DISTAL     | 054-0403-4004 |
| L 4mm LL/RM DISTAL     | 054-0400-4204 |
| L 4mm POSTERIOR        | 054-0404-5104 |
| XL 4mm LM/RL DISTAL    | 054-0403-5004 |
| XL 4mm LL/RM DISTAL    | 054-0400-5204 |
| XL 4mm POSTERIOR       | 054-0404-6104 |
| XXL 4mm LM/RL DISTAL * | 054-0403-6004 |
| XXL 4mm LL/RM DISTAL * | 054-0400-6204 |
| XXL 4mm POSTERIOR *    | 054-0404-7104 |

|                        |               |
|------------------------|---------------|
| <b>8mm</b>             |               |
| XXS 8mm LM/RL DISTAL * | 054-0403-0008 |
| XXS 8mm LL/RM DISTAL * | 054-0400-0208 |
| XXS 8mm POSTERIOR *    | 054-0404-1108 |
| XS 8mm LM/RL DISTAL    | 054-0403-1008 |
| XS 8mm LL/RM DISTAL    | 054-0400-1208 |
| XS 8mm POSTERIOR       | 054-0404-2108 |
| S 8mm LM/RL DISTAL     | 054-0403-2008 |
| S 8mm LL/RM DISTAL     | 054-0400-2208 |
| S 8mm POSTERIOR        | 054-0404-3108 |
| M 8mm LM/RL DISTAL     | 054-0403-3008 |
| M 8mm LL/RM DISTAL     | 054-0400-3208 |
| M 8mm POSTERIOR        | 054-0404-4108 |
| L 8mm LM/RL DISTAL     | 054-0403-4008 |
| L 8mm LL/RM DISTAL     | 054-0400-4208 |
| L 8mm POSTERIOR        | 054-0404-5108 |
| XL 8mm LM/RL DISTAL    | 054-0403-5008 |
| XL 8mm LL/RM DISTAL    | 054-0400-5208 |
| XL 8mm POSTERIOR       | 054-0404-6108 |
| XXL 8mm LM/RL DISTAL * | 054-0403-6008 |
| XXL 8mm LL/RM DISTAL * | 054-0400-6208 |
| XXL 8mm POSTERIOR *    | 054-0404-7108 |

|                         |               |
|-------------------------|---------------|
| <b>12mm</b>             |               |
| XXS 12mm LM/RL DISTAL * | 054-0403-0012 |
| XXS 12mm LL/RM DISTAL * | 054-0400-0212 |
| XXS 12mm POSTERIOR *    | 054-0404-1112 |
| XS 12mm LM/RL DISTAL    | 054-0403-1012 |
| XS 12mm LL/RM DISTAL    | 054-0400-1212 |
| XS 12mm POSTERIOR       | 054-0404-2112 |
| S 12mm LM/RL DISTAL     | 054-0403-2012 |
| S 12mm LL/RM DISTAL     | 054-0400-2212 |
| S 12mm POSTERIOR        | 054-0404-3112 |
| M 12mm LM/RL DISTAL     | 054-0403-3012 |
| M 12mm LL/RM DISTAL     | 054-0400-3212 |
| M 12mm POSTERIOR        | 054-0404-4112 |
| L 12mm LM/RL DISTAL     | 054-0403-4012 |
| L 12mm LL/RM DISTAL     | 054-0400-4212 |
| L 12mm POSTERIOR        | 054-0404-5112 |
| XL 12mm LM/RL DISTAL    | 054-0403-5012 |
| XL 12mm LL/RM DISTAL    | 054-0400-5212 |
| XL 12mm POSTERIOR       | 054-0404-6112 |
| XXL 12mm LM/RL DISTAL * | 054-0403-6012 |
| XXL 12mm LL/RM DISTAL * | 054-0400-6212 |
| XXL 12mm POSTERIOR *    | 054-0404-7112 |

  
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**"Movement is Life"**

REF:  
VB-004-PROSP-PC-04-EN-00

Revision:  
1

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07.01.2020

CE 1011



**EC CERTIFICATE**  
**Full Quality Assurance System**

**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

**No. 5-903-200-2103**

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.  
certifies that the manufacturer:

**Biotech GmbH**  
**Hagenauer Str. 17-19**  
**65203 Wiesbaden**  
**Germany**

for the products / product category:

**Sterile and non-sterile orthopaedic implant systems**

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **NE/1010/2021**

This certificate is valid together with EC Design-Examination Certificates according to Directive 93/42/EEC on Medical Devices, Annex II (4) **No. 5-904-204-2103** and **No. 5-905-204-2103**.

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2021-03-09

  
**László Imre**  
Managing Director



**EMKI 2680**

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.  
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

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[www.emki.hu](http://www.emki.hu)





# ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

## Additional information for Certificate No. 5-903-200-2103

The certificate is valid for the following manufacturing sites / facilities:

**Biotech GmbH**  
Hagenauer Str. 17-19  
65203 Wiesbaden, Germany

**Biotech GmbH Magyarországi Fióktelepe**  
Petőfi Sándor utca 43-47  
2049 Diósd, Hungary

The certificate is valid for the following products:

| <i>Sterile and non-sterile orthopaedic implant systems</i>                 | <i>Class</i> |
|----------------------------------------------------------------------------|--------------|
| Biotech Sterile Knee Endoprosthesis Systems                                | III          |
| Instruments and Trial Tray for Biotech Sterile Knee Endoprosthesis Systems | IIa          |
| Biotech Sterile Hip Endoprosthesis Systems                                 | III          |
| Instruments and Trial Tray for Biotech Sterile Hip Endoprosthesis Systems  | IIa          |
| Biotech Traumatological Implant Systems for Osteosynthesis                 | IIb          |
| Biotech Pectus Bar Correct System                                          | IIb          |
| Biotech Spinal Implant System                                              | IIb          |

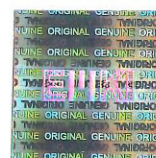
The detailed product list is kept by NEOEMKI LLC. under No. 1010/2020.

Issue: 1

Date: 2021-03-09

First issued: 2021-03-09

László Imre  
Managing Director



EMKI

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.  
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# EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical Devices, Annex II (4)

No. 5-904-204-2103

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.  
certifies that the following manufacturer's

**Biotech GmbH**  
**Hagenauer Str. 17-19**  
**65203 Wiesbaden**  
**Germany**

product's

**Biotech Sterile Knee Endoprosthesis System**  
(models listed in the attachment)

design dossier conforms to the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the report on the examination of the design dossier: **NE/1010/2021**

This certificate is valid only together with EC Certificate according to Directive 93/42/EEC on Medical Devices, Annex II excluding (4) No. **5-903-200-2103**.

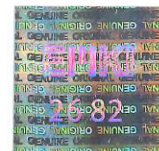
This certificate is valid until: **2024-05-26**

Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2021-03-09

  
László Imre  
Managing Director



EMKI 2682

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.  
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

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[www.emki.hu](http://www.emki.hu)





# ATTACHMENT TO EC DESIGN-EXAMINATION CERTIFICATE

Page 1 of 1

## Additional information for Certificate No. 5-904-204-2103

The certificate is valid for the following manufacturing sites / facilities:

**Biotech GmbH**  
Hagenauer Str. 17-19  
65203 Wiesbaden  
Germany

**Biotech GmbH Magyarországi Fióktelepe**  
Petőfi Sándor utca 43-47  
2049 Diósd  
Hungary

The certificate is valid for the following products / models:

### **Biotech Sterile Knee Endoprosthesis System**

|                                 | Class |
|---------------------------------|-------|
| TP Total Knee System            | III   |
| TRK Total Revision Knee System  | III   |
| Future Knee Modular System      | III   |
| Future Knee 1 System            | III   |
| HF - High Flexion Knee System   | III   |
| Biotech Constrained Knee System | III   |
| BMI Unicondylar Knee System     | III   |
| TMB Total Rotating Knee System  | III   |

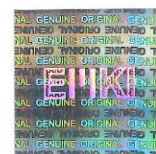
The detailed product list is kept by NEOEMKI LLC. under No. 1010/2020.

Issue: 1

Date: 2021-03-09

First issued: 2021-03-09

  
László Imre  
Managing Director



EMKI

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# EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical Devices, Annex II (4)

No. 5-905-204-2103

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.  
certifies that the following manufacturer's

**Biotech GmbH**  
**Hagenauer Str. 17-19**  
**65203 Wiesbaden**  
**Germany**

product's

**Biotech Sterile Hip Endoprosthesis System**  
(models listed in the attachment)

design dossier conforms to the requirements of Directive 93/42/EEC concerning medical  
devices, Annex II.

Registry number of the report on the examination of the design dossier: **NE/1010/2021**

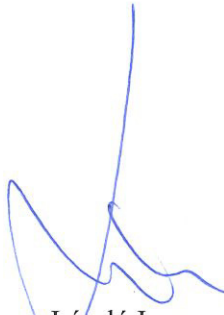
This certificate is valid only together with EC Certificate according to Directive 93/42/EEC on  
Medical Devices, Annex II excluding (4) No. **5-903-200-2103**.

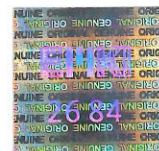
This certificate is valid until: **2024-05-26**

Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2021-03-09

  
László Imre  
Managing Director



EMKI 2684

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.  
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# ATTACHMENT TO EC DESIGN-EXAMINATION CERTIFICATE

Page 1 of 1

## Additional information for Certificate No. 5-905-204-2103

The certificate is valid for the following manufacturing sites / facilities:

**Biotech GmbH**  
Hagenauer Str. 17-19  
65203 Wiesbaden  
Germany

**Biotech GmbH Magyarországi Fióktelepe**  
Petőfi Sándor utca 43-47  
2049 Diósd  
Hungary

The certificate is valid for the following products / models:

### **Biotech Sterile Hip Endoprosthesis System**

|                                          | Class |
|------------------------------------------|-------|
| Biotech Modular Head System              | III   |
| Biotech Acetabular Cup System            | III   |
| BA Hip Stem System                       | III   |
| SKM Hip Stem System                      | III   |
| BET Hip Stem System                      | III   |
| BQS Hip Stem System                      | III   |
| Biotech Modular Revision Hip Stem System | III   |
| Austin Moore Hip Stem System             | III   |

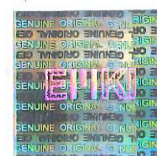
The detailed product list is kept by NEOEMKI LLC. under No. 1010/2020.

Issue: 1

Date: 2021-03-09

First issued: 2021-03-09

  
László Imre  
Managing Director



EMKI

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[www.emki.hu](http://www.emki.hu)



# QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-561-135-2112

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

as a Certification Body with ID No. NAH-4-0009/2021/K  
accredited by the National Accreditation Authority for management system certification  
certifies that the quality management system applied by

**BIOTECH GmbH**  
**Hagenauer Str. 17-19, 65203 Wiesbaden**  
**Germany**  
**and**  
**Magyarországi Fióktelepe**  
**Petőfi Sándor utca 43-47, 2049 Diósd**  
**Hungary**

meets the requirements of standard

**EN ISO 13485:2016**

in the field:

**Design, development, manufacture and distribution  
of non active surgical implant systems;  
Design, development, manufacture and distribution  
of surgical instrument systems**

Registry number of the related audit report: **NE/1010/2021**

This certificate is valid until **2024-09-08** supposed that the results of the regular yearly  
surveillance audits are satisfactory.

Budapest, 2021-12-30

  
László Imre  
Managing Director



EMKI 2796

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.  
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