



## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 075731 0075 Rev. 00**

**Manufacturer:** **Limacorporate S.p.A.**  
Via Nazionale, 52  
33038 Villanova San Daniele del Friuli (UDINE)  
ITALY

**SRN Manufacturer:** IT-MF-000010690

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G70 075731 0075 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G70_075731_0075_Rev.00)

**Report No.:** ITA1659611

**Valid from:** 2022-10-10

**Valid until:** 2027-10-09

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-10-10



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<b>Classification:</b>	III
<b>Device Group:</b>	P090904020401 - UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS, MONOBLOCK, MADE OF POLYETHYLENE P090905020102 - REVISION KNEE PROSTHESES FIXED BEARING TIBIAL PLATES
<b>Basic UDI-DI:</b>	80333903K000DR
<b>Intended Purpose:</b>	Physica ZUK Unicompartmental Knee System is intended for the cemented knee joint replacement and for long-term implantation inside the human body.
<b>Device(s):</b>	All-poly Tibial Component (UHMWPE + AISI316L)
<b>Classification:</b>	III
<b>Device Group:</b>	P090904020202 - UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL INSERTS, FIXED P090905020202 - REVISION KNEE PROSTHESES FIXED BEARING TIBIAL INSERTS
<b>Basic UDI-DI:</b>	80333903K000DR
<b>Intended Purpose:</b>	Physica ZUK Unicompartmental Knee System is intended for the cemented knee joint replacement and for long-term implantation inside the human body.
<b>Device(s):</b>	Articular Surface (UHMWPE)
<b>Classification:</b>	III
<b>Device Group:</b>	P090904020103 - FIXED CEMENTED UNICOMPARTMENTAL PRIMARY IMPLANT TIBIAL PLATES P090905020102 - REVISION KNEE PROSTHESES FIXED BEARING TIBIAL PLATES
<b>Basic UDI-DI:</b>	80333903K000DR
<b>Intended Purpose:</b>	Physica ZUK Unicompartmental Knee System is intended for the cemented knee joint replacement and for long-term implantation inside the human body.
<b>Device(s):</b>	Tibial Component (Ti6Al4V +PMMA)
<b>Classification:</b>	III
<b>Device Group:</b>	P0909040101 - UNICOMPARTMENTAL KNEE PROSTHESES FEMORAL COMPONENTS (UNICONDYLAR), CEMENTED P09090501 - REVISION KNEE PROSTHESES FEMORAL COMPONENTS
<b>Basic UDI-DI:</b>	80333903K000DR
<b>Intended Purpose:</b>	Physica ZUK Unicompartmental Knee System is intended for the cemented knee joint replacement and for long-term implantation inside the human body.
<b>Device(s):</b>	Femoral Component (CoCrMo + PMMA)



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The validity of this certificate -  
 depends on conditions and/or  
 is limited to the following:

### All-poly Tibial Component (UHMWPE + AISI316L)

Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 8mm Height	00-5842-031-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 10mm Height	00-5842-031-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 12mm Height	00-5842-031-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 14mm Height	00-5842-031-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 8mm Height	00-5842-032-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 10mm Height	00-5842-032-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 12mm Height	00-5842-032-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 1, 14mm Height	00-5842-032-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 8mm Height	00-5842-041-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 10mm Height	00-5842-041-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 12mm Height	00-5842-041-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 14mm Height	00-5842-041-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 8mm Height	00-5842-042-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 10mm Height	00-5842-042-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 12mm Height	00-5842-042-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 2, 14mm Height	00-5842-042-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 8mm Height	00-5842-051-08



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Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 10mm Height	00-5842-051-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 12mm Height	00-5842-051-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 14mm Height	00-5842-051-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 8mm Height	00-5842-052-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 10mm Height	00-5842-052-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 12mm Height	00-5842-052-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 3, 14mm Height	00-5842-052-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 8mm Height	00-5842-061-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 10mm Height	00-5842-061-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 12mm Height	00-5842-061-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 14mm Height	00-5842-061-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 8mm Height	00-5842-062-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 10mm Height	00-5842-062-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 12mm Height	00-5842-062-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 4, 14mm Height	00-5842-062-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 8mm Height	00-5842-071-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 10mm Height	00-5842-071-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 12mm Height	00-5842-071-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 14mm Height	00-5842-071-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 8mm Height	00-5842-072-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial	00-5842-072-10



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Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 10mm Height	
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 12mm Height	00-5842-072-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 5, 14mm Height	00-5842-072-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 8mm Height	00-5842-081-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 10mm Height	00-5842-081-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 12mm Height	00-5842-081-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Left Medial/Right Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 14mm Height	00-5842-081-14
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 8mm Height	00-5842-082-08
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 10mm Height	00-5842-082-10
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 12mm Height	00-5842-082-12
Physica ZUK Unicompartmental Knee System, All-Poly Tibial Component, Right Medial/Left Lateral, Femoral Size A,B,C,D,E,F,G, Size 6, 14mm Height	00-5842-082-14

### Articular Surface (UHMWPE)

Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 1, 8mm Height	00-5842-021-08
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 1, 9mm Height	00-5842-021-09
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 1, 10mm Height	00-5842-021-10
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 1, 11mm Height	00-5842-021-11
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 1, 12mm Height	00-5842-021-12
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 1, 14mm Height	00-5842-021-14
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 2, 8mm Height	00-5842-022-08
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 2, 9mm Height	00-5842-022-09
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 2, 10mm Height	00-5842-022-10





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Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 2, 11mm Height	00-5842-022-11
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 2, 12mm Height	00-5842-022-12
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 2, 14mm Height	00-5842-022-14
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 3, 8mm Height	00-5842-023-08
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 3, 9mm Height	00-5842-023-09
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 3, 10mm Height	00-5842-023-10
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 3, 11mm Height	00-5842-023-11
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 3, 12mm Height	00-5842-023-12
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 3, 14mm Height	00-5842-023-14
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 4, 8mm Height	00-5842-024-08
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 4, 9mm Height	00-5842-024-09
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 4, 10mm Height	00-5842-024-10
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 4, 11mm Height	00-5842-024-11
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 4, 12mm Height	00-5842-024-12
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 4, 14mm Height	00-5842-024-14
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 5, 8mm Height	00-5842-025-08
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 5, 9mm Height	00-5842-025-09
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 5, 10mm Height	00-5842-025-10
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 5, 11mm Height	00-5842-025-11
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 5, 12mm Height	00-5842-025-12
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 5, 14mm Height	00-5842-025-14
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 6, 8mm Height	00-5842-026-08
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 6, 9mm Height	00-5842-026-09
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 6, 10mm Height	00-5842-026-10



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Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 6, 11mm Height	00-5842-026-11
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 6, 12mm Height	00-5842-026-12
Physica ZUK Unicompartmental Knee System, Articular Surface, Femoral Size A,B,C,D,E,F,G, Size 6, 14mm Height	00-5842-026-14

### Tibial Component (Ti6Al4V +PMMA)

Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Left Medial/Right Lateral, Size 1	00-5842-001-01
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Right Medial/Left Lateral, Size 1	00-5842-001-02
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Left Medial/Right Lateral, Size 2	00-5842-002-01
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Right Medial/Left Lateral, Size 2	00-5842-002-02
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Left Medial/Right Lateral, Size 3	00-5842-003-01
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Right Medial/Left Lateral, Size 3	00-5842-003-02
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Left Medial/Right Lateral, Size 4	00-5842-004-01
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Right Medial/Left Lateral, Size 4	00-5842-004-02
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Left Medial/Right Lateral, Size 5	00-5842-005-01
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Right Medial/Left Lateral, Size 5	00-5842-005-02
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Left Medial/Right Lateral, Size 6	00-5842-006-01
Physica ZUK Unicompartmental Knee System, Tibial Component, Precoat, Right Medial/Left Lateral, Size 6	00-5842-006-02

### Femoral Component (CoCrMo + PMMA)

Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size A	00-5842-011-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size A	00-5842-011-02
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size B	00-5842-012-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size B	00-5842-012-02



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Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size C	00-5842-013-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size C	00-5842-013-02
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size D	00-5842-014-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size D	00-5842-014-02
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size E	00-5842-015-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size E	00-5842-015-02
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size F	00-5842-016-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size F	00-5842-016-02
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Left Medial/Right Lateral, Size G	00-5842-017-01
Physica ZUK Unicompartmental Knee System, Femoral Component, Precoat, Right Medial/Left Lateral, Size G	00-5842-017-02