

EC Design-Examination Certificate

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

No.**CE 671275**

Issued To:

**United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan**

In respect of:

U2 Total Knee System-PSA

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-08-27**Date: **2020-06-19**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

**United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan**

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2103-5110	Femoral component, PSA, #1, left	Total Knee Replacement	Class III
2103-5120	Femoral component, PSA, #2, left		
2103-5130	Femoral component, PSA, #3, left		
2103-5140	Femoral component, PSA, #4, left		
2103-5150	Femoral component, PSA, #5, left		
2103-5160	Femoral component, PSA, #6, left		
2103-5210	Femoral component, PSA, #1, right		
2103-5220	Femoral component, PSA, #2, right		
2103-5230	Femoral component, PSA, #3, right		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2103-5240	Femoral component, PSA, #4, right	Total Knee Replacement	Class III
2103-5250	Femoral component, PSA, #5, right		
2103-5260	Femoral component, PSA, #6, right		
2303-5011	Tibial insert, PSA, #1, 9mm thick		
2303-5012	Tibial insert, PSA, #1, 11mm thick		
2303-5013	Tibial insert, PSA, #1, 13mm thick		
2303-5014	Tibial insert, PSA, #1, 15mm thick		
2303-5015	Tibial insert, PSA, #1, 18mm thick		
2303-5016	Tibial insert, PSA, #1, 21mm thick		
2303-5017	Tibial insert, PSA, #1, 25mm thick		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

**United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan**

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2303-5018	Tibial insert, PSA, #1, 30mm thick	Total Knee Replacement	Class III
2303-5021	Tibial insert, PSA, #2, 9mm thick		
2303-5022	Tibial insert, PSA, #2, 11mm thick		
2303-5023	Tibial insert, PSA, #2, 13mm thick		
2303-5024	Tibial insert, PSA, #2, 15mm thick		
2303-5025	Tibial insert, PSA, #2, 18mm thick		
2303-5026	Tibial insert, PSA, #2, 21mm thick		
2303-5027	Tibial insert, PSA, #2, 25mm thick		
2303-5028	Tibial insert, PSA, #2, 30mm thick		
2303-5031	Tibial insert, PSA, #3, 9mm thick		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 4 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2303-5032	Tibial insert, PSA, #3, 11mm thick	Total Knee Replacement	Class III
2303-5033	Tibial insert, PSA, #3, 13mm thick		
2303-5034	Tibial insert, PSA, #3, 15mm thick		
2303-5035	Tibial insert, PSA, #3, 18mm thick		
2303-5036	Tibial insert, PSA, #3, 21mm thick		
2303-5037	Tibial insert, PSA, #3, 25mm thick		
2303-5038	Tibial insert, PSA, #3, 30mm thick		
2303-5041	Tibial insert, PSA, #4, 9mm thick		
2303-5042	Tibial insert, PSA, #4, 11mm thick		
2303-5043	Tibial insert, PSA, #4, 13mm thick		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2303-5044	Tibial insert, PSA, #4, 15mm thick	Total Knee Replacement	Class III
2303-5045	Tibial insert, PSA, #4, 18mm thick		
2303-5046	Tibial insert, PSA, #4, 21mm thick		
2303-5047	Tibial insert, PSA, #4, 25mm thick		
2303-5048	Tibial insert, PSA, #4, 30mm thick		
2303-5051	Tibial insert, PSA, #5, 9mm thick		
2303-5052	Tibial insert, PSA, #5, 11mm thick		
2303-5053	Tibial insert, PSA, #5, 13mm thick		
2303-5054	Tibial insert, PSA, #5, 15mm thick		
2303-5055	Tibial insert, PSA, #5, 18mm thick		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2303-5056	Tibial insert, PSA, #5, 21mm thick	Total Knee Replacement	Class III
2303-5057	Tibial insert, PSA, #5, 25mm thick		
2303-5058	Tibial insert, PSA, #5, 30mm thick		
2303-5061	Tibial insert, PSA, #6, 9mm thick		
2303-5062	Tibial insert, PSA, #6, 11mm thick		
2303-5063	Tibial insert, PSA, #6, 13mm thick		
2303-5064	Tibial insert, PSA, #6, 15mm thick		
2303-5065	Tibial insert, PSA, #6, 18mm thick		
2303-5066	Tibial insert, PSA, #6, 21mm thick		
2303-5067	Tibial insert, PSA, #6, 25mm thick		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

**United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan**

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2303-5068	Tibial insert, PSA, #6, 30mm thick	Total Knee Replacement	Class III
2203-5010	Tibial Baseplate, PSA, #1		
2203-5020	Tibial Baseplate, PSA, #2		
2203-5030	Tibial Baseplate, PSA, #3		
2203-5040	Tibial Baseplate, PSA, #4		
2203-5050	Tibial Baseplate, PSA, #5		
2203-5060	Tibial Baseplate, PSA, #6		
2203-5210	Tibial Baseplate, PSA, Screw locking, #1		
2203-5220	Tibial Baseplate, PSA, Screw locking, #2		
2203-5230	Tibial Baseplate, PSA, Screw locking, #3		
2203-5240	Tibial Baseplate, PSA, Screw locking, #4		
2203-5250	Tibial Baseplate, PSA, Screw locking, #5		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 8 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2203-5260	Tibial Baseplate, PSA, Screw locking, #6	Total Knee Replacement	Class III
2703-5003	Straight stem, PSA, Ø14x30mm		
2703-5011	Straight stem, PSA, Ø10x75mm		
2703-5112	Straight stem, PSA, Ø11x75mm		
2703-5012	Straight stem, PSA, Ø12x75mm		
2703-5113	Straight stem, PSA, Ø13x75mm		
2703-5013	Straight stem, PSA, Ø14x75mm		
2703-5114	Straight stem, PSA, Ø15x75mm		
2703-5014	Straight stem, PSA, Ø16x75mm		
2703-5115	Straight stem, PSA, Ø17x75mm		
2703-5015	Straight stem, PSA, Ø18x75mm		
2703-5116	Straight stem, PSA, Ø19x75mm		
2703-5016	Straight stem, PSA, Ø20x75mm		
2703-5117	Straight stem, PSA, Ø21x75mm		
2703-5017	Straight stem, PSA, Ø22x75mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5118	Straight stem, PSA, Ø23x75mm	Total Knee Replacement	Class III
2703-5018	Straight stem, PSA, Ø24x75mm		
2703-5021	Straight stem, PSA, Ø10x100mm		
2703-5122	Straight stem, PSA, Ø11x100mm		
2703-5022	Straight stem, PSA, Ø12x100mm		
2703-5123	Straight stem, PSA, Ø13x100mm		
2703-5023	Straight stem, PSA, Ø14x100mm		
2703-5124	Straight stem, PSA, Ø15x100mm		
2703-5024	Straight stem, PSA, Ø16x100mm		
2703-5125	Straight stem, PSA, Ø17x100mm		
2703-5025	Straight stem, PSA, Ø18x100mm		
2703-5126	Straight stem, PSA, Ø19x100mm		
2703-5026	Straight stem, PSA, Ø20x100mm		
2703-5127	Straight stem, PSA, Ø21x100mm		
2703-5027	Straight stem, PSA, Ø22x100mm		
2703-5128	Straight stem, PSA, Ø23x100mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5028	Straight stem, PSA, Ø24x100mm	Total Knee Replacement	Class III
2703-5051	Straight stem, PSA, Ø10x150mm		
2703-5052	Straight stem, PSA, Ø12x150mm		
2703-5053	Straight stem, PSA, Ø14x150mm		
2703-5054	Straight stem, PSA, Ø16x150mm		
2703-5055	Straight stem, PSA, Ø18x150mm		
2703-5056	Straight stem, PSA, Ø20x150mm		
2703-5057	Straight stem, PSA, Ø22x150mm		
2703-5058	Straight stem, PSA, Ø24x150mm		
2703-5152	Straight stem, PSA, Ø11x150mm		
2703-5153	Straight stem, PSA, Ø13x150mm		
2703-5154	Straight stem, PSA, Ø15x150mm		
2703-5155	Straight stem, PSA, Ø17x150mm		
2703-5156	Straight stem, PSA, Ø19x150mm		
2703-5157	Straight stem, PSA, Ø21x150mm		
2703-5158	Straight stem, PSA, Ø23x150mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5061	Straight stem, PSA, Ø10x200mm	Total Knee Replacement	Class III
2703-5062	Straight stem, PSA, Ø12x200mm		
2703-5063	Straight stem, PSA, Ø14x200mm		
2703-5064	Straight stem, PSA, Ø16x200mm		
2703-5065	Straight stem, PSA, Ø18x200mm		
2703-5066	Straight stem, PSA, Ø20x200mm		
2703-5067	Straight stem, PSA, Ø22x200mm		
2703-5068	Straight stem, PSA, Ø24x200mm		
2703-5162	Straight stem, PSA, Ø11x200mm		
2703-5163	Straight stem, PSA, Ø13x200mm		
2703-5164	Straight stem, PSA, Ø15x200mm		
2703-5165	Straight stem, PSA, Ø17x200mm		
2703-5166	Straight stem, PSA, Ø19x200mm		
2703-5167	Straight stem, PSA, Ø21x200mm		
2703-5168	Straight stem, PSA, Ø23x200mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 12 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5081	Straight stem, PSA, $\phi 10 \times 240\text{mm}$	Total Knee Replacement	Class III
2703-5082	Straight stem, PSA, $\phi 12 \times 240\text{mm}$		
2703-5083	Straight stem, PSA, $\phi 14 \times 240\text{mm}$		
2703-5084	Straight stem, PSA, $\phi 16 \times 240\text{mm}$		
2703-5085	Straight stem, PSA, $\phi 18 \times 240\text{mm}$		
2703-5086	Straight stem, PSA, $\phi 20 \times 240\text{mm}$		
2703-5087	Straight stem, PSA, $\phi 22 \times 240\text{mm}$		
2703-5088	Straight stem, PSA, $\phi 24 \times 240\text{mm}$		
2703-5182	Straight stem, PSA, $\phi 11 \times 240\text{mm}$		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5183	Straight stem, PSA, $\phi 13 \times 240 \text{mm}$	Total Knee Replacement	Class III
2703-5184	Straight stem, PSA, $\phi 15 \times 240 \text{mm}$		
2703-5185	Straight stem, PSA, $\phi 17 \times 240 \text{mm}$		
2703-5186	Straight stem, PSA, $\phi 19 \times 240 \text{mm}$		
2703-5187	Straight stem, PSA, $\phi 21 \times 240 \text{mm}$		
2703-5188	Straight stem, PSA, $\phi 23 \times 240 \text{mm}$		
2703-5211	Straight stem, PSA, Cemented, $\text{Ø}10 \times 75 \text{mm}$		
2703-5212	Straight stem, PSA, Cemented, $\text{Ø}12 \times 75 \text{mm}$		
2703-5213	Straight stem, PSA, Cemented, $\text{Ø}14 \times 75 \text{mm}$		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 14 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5214	Straight stem, PSA, Cemented, Ø16x75mm	Total Knee Replacement	Class III
2703-5215	Straight stem, PSA, Cemented, Ø18x75mm		
2703-5216	Straight stem, PSA, Cemented, Ø20x75mm		
2703-5217	Straight stem, PSA, Cemented, Ø22x75mm		
2703-5221	Straight stem, PSA, Cemented, Ø10x100mm		
2703-5222	Straight stem, PSA, Cemented, Ø12x100mm		
2703-5223	Straight stem, PSA, Cemented, Ø14x100mm		
2703-5224	Straight stem, PSA, Cemented, Ø16x100mm		
2703-5225	Straight stem, PSA, Cemented, Ø18x100mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 15 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5226	Straight stem, PSA, Cemented, Ø20x100mm	Total Knee Replacement	Class III
2703-5227	Straight stem, PSA, Cemented, Ø22x100mm		
2703-5031	Curved stem, PSA, Ø10x150mm		
2703-5132	Curved stem, PSA, Ø11x150mm		
2703-5032	Curved stem, PSA, Ø12x150mm		
2703-5133	Curved stem, PSA, Ø13x150mm		
2703-5033	Curved stem, PSA, Ø14x150mm		
2703-5134	Curved stem, PSA, Ø15x150mm		
2703-5034	Curved stem, PSA, Ø16x150mm		
2703-5135	Curved stem, PSA, Ø17x150mm		
2703-5035	Curved stem, PSA, Ø18x150mm		
2703-5136	Curved stem, PSA, Ø19x150mm		
2703-5036	Curved stem, PSA, Ø20x150mm		
2703-5137	Curved stem, PSA, Ø21x150mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5037	Curved stem, PSA, Ø22x150mm	Total Knee Replacement	Class III
2703-5138	Curved stem, PSA, Ø23x150mm		
2703-5038	Curved stem, PSA, Ø24x150mm		
2703-5041	Curved stem, PSA, Ø10x200mm		
2703-5142	Curved stem, PSA, Ø11x200mm		
2703-5042	Curved stem, PSA, Ø12x200mm		
2703-5143	Curved stem, PSA, Ø13x200mm		
2703-5043	Curved stem, PSA, Ø14x200mm		
2703-5144	Curved stem, PSA, Ø15x200mm		
2703-5044	Curved stem, PSA, Ø16x200mm		
2703-5145	Curved stem, PSA, Ø17x200mm		
2703-5045	Curved stem, PSA, Ø18x200mm		
2703-5146	Curved stem, PSA, Ø19x200mm		
2703-5046	Curved stem, PSA, Ø20x200mm		
2703-5147	Curved stem, PSA, Ø21x200mm		
2703-5047	Curved stem, PSA, Ø22x200mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5148	Curved stem, PSA, Ø23x200mm	Total Knee Replacement	Class III
2703-5048	Curved stem, PSA, Ø24x200mm		
2703-5071	Curved stem, PSA, Ø10x240mm		
2703-5072	Curved stem, PSA, Ø12x240mm		
2703-5073	Curved stem, PSA, Ø14x240mm		
2703-5074	Curved stem, PSA, Ø16x240mm		
2703-5075	Curved stem, PSA, Ø18x240mm		
2703-5076	Curved stem, PSA, Ø20x240mm		
2703-5077	Curved stem, PSA, Ø22x240mm		
2703-5078	Curved stem, PSA, Ø24x240mm		
2703-5172	Curved stem, PSA, Ø11x240mm		
2703-5173	Curved stem, PSA, Ø13x240mm		
2703-5174	Curved stem, PSA, Ø15x240mm		
2703-5175	Curved stem, PSA, Ø17x240mm		
2703-5176	Curved stem, PSA, Ø19x240mm		
2703-5177	Curved stem, PSA, Ø21x240mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5178	Curved stem, PSA, Ø23x240mm	Total Knee Replacement	Class III
2703-5231	Curved stem, PSA, Cemented, Ø10x150mm		
2703-5232	Curved stem, PSA, Cemented, Ø12x150mm		
2703-5233	Curved stem, PSA, Cemented, Ø14x150mm		
2703-5234	Curved stem, PSA, Cemented, Ø16x150mm		
2703-5235	Curved stem, PSA, Cemented, Ø18x150mm		
2703-5236	Curved stem, PSA, Cemented, Ø20x150mm		
2703-5237	Curved stem, PSA, Cemented, Ø22x150mm		
2703-5241	Curved stem, PSA, Cemented, Ø10x200mm		
2703-5242	Curved stem, PSA, Cemented, Ø12x200mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

Catalogue Number	Device Name	Intended purpose per IFU	Classification
2703-5243	Curved stem, PSA, Cemented, Ø14x200mm	Total Knee Replacement	Class III
2703-5244	Curved stem, PSA, Cemented, Ø16x200mm		
2703-5245	Curved stem, PSA, Cemented, Ø18x200mm		
2703-5246	Curved stem, PSA, Cemented, Ø20x200mm		
2703-5247	Curved stem, PSA, Cemented, Ø22x200mm		
2903-1012	Femoral screw, PSA, M5x12mm		
2903-1014	Femoral screw, PSA, M5x14mm		
2903-1016	Femoral screw, PSA, M5x16mm		

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 20 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 671275

Issued To:

**United Orthopedic Corporation
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan**

Certificate History

Date	Reference Number	Action
27 August 2019	8718244	First issue. Transfer from another notified body.
Current	3154370	Certificate Renewal.

First Issued: **2019-08-27**

Date: **2020-06-19**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 21 of 21

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Declaration of Conformity

For the following equipment:

Accessories for total joint replacement

(Product list is shown as following pages)

UMDNS code: 13158, Prosthesis, joint, internal

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance of conformity assessment **Annex II-exclusive section 4** to be certified by British Standards Institution (notified body number – 2797).

For the evaluation regarding the **Class IIb** product safety aspects, the following **harmonized standards** are applied:

EN ISO 14630, EN ISO 21534, EN ISO 13485, EN ISO 15223-1, EN 556-1, EN 1041, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-3, EN ISO 10993-5, EN ISO 10993-6, EN ISO 10993-11, EN ISO 11137-1, EN ISO 11137-2, EN ISO 11737-1, EN ISO 11737-2, EN 868-5

The following European Authorized Representative is stated to the declaration:

mdi Europa GmbH / Langenhagener Straße 71, 30855 Langenhagen, Germany

(Company Name / Address)

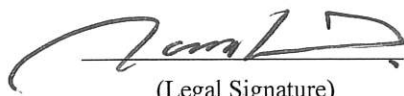
This declaration is issued under the sole responsibility of United Orthopedic Corporation. The following person is responsible for the compliance of declaration:

United Orthopedic Corporation / No. 57, Park Ave. 2, Science Park, Hsinchu City 30075, Taiwan

(Manufacturer Name / Address)

Jason Lin / President

(Name / Position)


(Legal Signature)

2020.11.30

(Date)

Catalog Number	Product Name
5200-6515	Co-Cr cancellous bone screw,15mm
5200-6520	Co-Cr cancellous bone screw,20mm
5200-6525	Co-Cr cancellous bone screw,25mm
5200-6530	Co-Cr cancellous bone screw,30mm
5200-6535	Co-Cr cancellous bone screw,35mm
5200-6540	Co-Cr cancellous bone screw,40mm
5201-6715	U2 Acetabular component, Titanium cancellous bone screw, 15 mm
5201-6720	U2 Acetabular component, Titanium cancellous bone screw, 20 mm
5201-6725	U2 Acetabular component, Titanium cancellous bone screw, 25 mm
5201-6730	U2 Acetabular component, Titanium cancellous bone screw, 30 mm
5201-6735	U2 Acetabular component, Titanium cancellous bone screw, 35 mm
5201-6740	U2 Acetabular component, Titanium cancellous bone screw, 40 mm
5201-6745	U2 Acetabular component, Titanium cancellous bone screw, 45 mm
5201-6750	U2 Acetabular component, Titanium cancellous bone screw, 50 mm
5201-6755	U2 Acetabular component, Titanium cancellous bone screw, 55 mm
5201-6760	U2 Acetabular component, Titanium cancellous bone screw, 60mm
5206-1015	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 15mm Length
5206-1020	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 20mm Length
5206-1025	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 25mm Length
5206-1030	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 30mm Length
5206-1035	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 35mm Length
5206-1040	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 40mm Length
5206-1045	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 45mm Length
5206-1050	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 50mm Length

5206-1055	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 55mm Length
5206-1060	United Hip System, Ti Cancellous Screw, 6.5mm Dia., 60mm Length
1301-1010	Center Hole Screw & plastic plug set
1301-1010-C	Center Hole Screw & plastic plug set, cemented
1306-1001	U-Motion II Set of screw hole covers

Catalog Number	Product Name
2603-5001	U2 Total Knee System, Femoral augment set, Posterior, #1, 3.5mm
2603-5002	U2 Total Knee System, Femoral augment set, Posterior, #2, 3.5mm
2603-5003	U2 Total Knee System, Femoral augment set, Posterior, #3, 3.5mm
2603-5004	U2 Total Knee System, Femoral augment set, Posterior, #4, 3.5mm
2603-5005	U2 Total Knee System, Femoral augment set, Posterior, #5, 3.5mm
2603-5006	U2 Total Knee System, Femoral augment set, Posterior, #6, 3.5mm
2603-5011	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #1, 4mm
2603-5021	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #2, 4mm
2603-5031	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #3, 4mm
2603-5041	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #4, 4mm
2603-5051	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #5, 4mm
2603-5061	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #6, 4mm
2603-5012	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #1, 8mm
2603-5022	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #2, 8mm
2603-5032	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #3, 8mm
2603-5042	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #4, 8mm
2603-5052	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #5, 8mm
2603-5062	U2 Total Knee System, Femoral Augment Set, PSA, Posterior, #6, 8mm
2603-5111	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 4mm, Left Medial / Right Lateral
2603-5121	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 4mm, Left Medial / Right Lateral
2603-5131	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 4mm, Left Medial / Right Lateral
2603-5141	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 4mm, Left Medial / Right Lateral
2603-5151	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 4mm, Left Medial / Right Lateral
2603-5161	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 4mm, Left Medial / Right Lateral

2603-5112	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 8mm, Left Medial / Right Lateral
2603-5122	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 8mm, Left Medial / Right Lateral
2603-5132	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 8mm, Left Medial / Right Lateral
2603-5142	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 8mm, Left Medial / Right Lateral
2603-5152	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 8mm, Left Medial / Right Lateral
2603-5162	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 8mm, Left Medial / Right Lateral
2603-5113	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 12mm, Left Medial / Right Lateral
2603-5123	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 12mm, Left Medial / Right Lateral
2603-5133	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 12mm, Left Medial / Right Lateral
2603-5143	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 12mm, Left Medial / Right Lateral
2603-5153	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 12mm, Left Medial / Right Lateral
2603-5163	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 12mm, Left Medial / Right Lateral
2603-5114	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 16mm, Left Medial / Right Lateral
2603-5124	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 16mm, Left Medial / Right Lateral
2603-5134	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 16mm, Left Medial / Right Lateral
2603-5144	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 16mm, Left Medial / Right Lateral
2603-5154	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 16mm, Left Medial / Right Lateral
2603-5164	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 16mm, Left Medial / Right Lateral
2603-5211	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 4mm, Right Medial / Left Lateral
2603-5221	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 4mm, Right Medial / Left Lateral
2603-5231	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 4mm, Right Medial / Left Lateral
2603-5241	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 4mm, Right Medial / Left Lateral
2603-5251	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 4mm, Right Medial / Left Lateral
2603-5261	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 4mm, Right Medial / Left Lateral
2603-5212	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 8mm, Right Medial / Left Lateral

2603-5222	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 8mm, Right Medial / Left Lateral
2603-5232	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 8mm, Right Medial / Left Lateral
2603-5242	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 8mm, Right Medial / Left Lateral
2603-5252	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 8mm, Right Medial / Left Lateral
2603-5262	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 8mm, Right Medial / Left Lateral
2603-5213	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 12mm, Right Medial / Left Lateral
2603-5223	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 12mm, Right Medial / Left Lateral
2603-5233	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 12mm, Right Medial / Left Lateral
2603-5243	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 12mm, Right Medial / Left Lateral
2603-5253	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 12mm, Right Medial / Left Lateral
2603-5263	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 12mm, Right Medial / Left Lateral
2603-5214	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #1, 16mm, Right Medial / Left Lateral
2603-5224	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #2, 16mm, Right Medial / Left Lateral
2603-5234	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #3, 16mm, Right Medial / Left Lateral
2603-5244	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #4, 16mm, Right Medial / Left Lateral
2603-5254	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #5, 16mm, Right Medial / Left Lateral
2603-5264	U2 Total Knee System, Femoral Augment Set, PSA, Distal, #6, 16mm, Right Medial / Left Lateral
2603-5301	U2 Total Knee System, Femoral augment, Posterior/Distal, left, #1, 4mm
2603-5302	U2 Total Knee System, Femoral augment, Posterior/Distal, left, #2, 4mm
2603-5303	U2 Total Knee System, Femoral augment, Posterior/Distal, left, #3, 4mm
2603-5304	U2 Total Knee System, Femoral augment, Posterior/Distal, left, #4, 4mm
2603-5305	U2 Total Knee System, Femoral augment, Posterior/Distal, left, #5, 4mm
2603-5306	U2 Total Knee System, Femoral augment, Posterior/Distal, left, #6, 4mm
2603-5401	U2 Total Knee System, Femoral augment, Posterior/Distal, right, #1, 4mm
2603-5402	U2 Total Knee System, Femoral augment, Posterior/Distal, right, #2, 4mm

2603-5403	U2 Total Knee System, Femoral augment, Posterior/Distal, right, #3, 4mm
2603-5404	U2 Total Knee System, Femoral augment, Posterior/Distal, right, #4, 4mm
2603-5405	U2 Total Knee System, Femoral augment, Posterior/Distal, right, #5, 4mm
2603-5406	U2 Total Knee System, Femoral augment, Posterior/Distal, right, #6, 4mm
2603-5313	U2 Total Knee System, Femoral Augment Set, Distal Only, #1, 12mm
2603-5323	U2 Total Knee System, Femoral Augment Set, Distal Only, #2, 12mm
2603-5333	U2 Total Knee System, Femoral Augment Set, Distal Only, #3, 12mm
2603-5343	U2 Total Knee System, Femoral Augment Set, Distal Only, #4, 12mm
2603-5353	U2 Total Knee System, Femoral Augment Set, Distal Only, #5, 12mm
2603-5363	U2 Total Knee System, Femoral Augment Set, Distal Only, #6, 12mm
2603-5314	U2 Total Knee System, Femoral Augment Set, Distal Only, #1, 16mm
2603-5324	U2 Total Knee System, Femoral Augment Set, Distal Only, #2, 16mm
2603-5334	U2 Total Knee System, Femoral Augment Set, Distal Only, #3, 16mm
2603-5344	U2 Total Knee System, Femoral Augment Set, Distal Only, #4, 16mm
2603-5354	U2 Total Knee System, Femoral Augment Set, Distal Only, #5, 16mm
2603-5364	U2 Total Knee System, Femoral Augment Set, Distal Only, #6, 16mm
2803-5011	U2 Total Knee System, Tibial augment, #1, 5mm
2803-5021	U2 Total Knee System, Tibial augment, #2, 5mm
2803-5031	U2 Total Knee System, Tibial augment, #3, 5mm
2803-5041	U2 Total Knee System, Tibial augment, #4, 5mm
2803-5051	U2 Total Knee System, Tibial augment, #5, 5mm
2803-5061	U2 Total Knee System, Tibial augment, #6, 5mm
2803-5012	U2 Total Knee System, Tibial augment, #1, 10mm
2803-5022	U2 Total Knee System, Tibial augment, #2, 10mm
2803-5032	U2 Total Knee System, Tibial augment, #3, 10mm

2803-5042	U2 Total Knee System, Tibial augment, #4, 10mm
2803-5052	U2 Total Knee System, Tibial augment, #5, 10mm
2803-5062	U2 Total Knee System, Tibial augment, #6, 10mm
2803-5013	U2 Total Knee System, Tibial augment, #1, 15mm
2803-5023	U2 Total Knee System, Tibial augment, #2, 15mm
2803-5033	U2 Total Knee System, Tibial augment, #3, 15mm
2803-5043	U2 Total Knee System, Tibial augment, #4, 15mm
2803-5053	U2 Total Knee System, Tibial augment, #5, 15mm
2803-5063	U2 Total Knee System, Tibial augment, #6, 15mm
2803-5111	U2 Total Knee System, Tibial augment, #1, 15mm
2803-5121	U2 Total Knee System, Tibial augment, #2, 15mm
2803-5131	U2 Total Knee System, Tibial augment, #3, 15mm
2803-5141	U2 Total Knee System, Tibial augment, #4, 15mm
2803-5151	U2 Total Knee System, Tibial augment, #5, 15mm
2803-5161	U2 Total Knee System, Tibial augment, #6, 15mm
2803-5112	U2 Total Knee System, Tibial augment, #1, 30mm
2803-5122	U2 Total Knee System, Tibial augment, #2, 30mm
2803-5132	U2 Total Knee System, Tibial augment, #3, 30mm
2803-5142	U2 Total Knee System, Tibial augment, #4, 30mm
2803-5152	U2 Total Knee System, Tibial augment, #5, 30mm
2803-5162	U2 Total Knee System, Tibial augment, #6, 30mm
2803-5201	U2 Total Knee System, Tibial Augment Set, Screw Locking, #0, 5mm Thick
2803-5211	U2 Total Knee System, Tibial Augment Set, Screw Locking, #1, 5mm Thick
2803-5221	U2 Total Knee System, Tibial Augment Set, Screw Locking, #2, 5mm Thick
2803-5231	U2 Total Knee System, Tibial Augment Set, Screw Locking, #3, 5mm Thick

2803-5241	U2 Total Knee System, Tibial Augment Set, Screw Locking, #4, 5mm Thick
2803-5251	U2 Total Knee System, Tibial Augment Set, Screw Locking, #5, 5mm Thick
2803-5261	U2 Total Knee System, Tibial Augment Set, Screw Locking, #6, 5mm Thick
2803-5271	U2 Total Knee System, Tibial Augment Set, Screw Locking, #7, 5mm Thick
2803-5202	U2 Total Knee System, Tibial Augment Set, Screw Locking, #0, 10mm Thick
2803-5212	U2 Total Knee System, Tibial Augment Set, Screw Locking, #1, 10mm Thick
2803-5222	U2 Total Knee System, Tibial Augment Set, Screw Locking, #2, 10mm Thick
2803-5232	U2 Total Knee System, Tibial Augment Set, Screw Locking, #3, 10mm Thick
2803-5242	U2 Total Knee System, Tibial Augment Set, Screw Locking, #4, 10mm Thick
2803-5252	U2 Total Knee System, Tibial Augment Set, Screw Locking, #5, 10mm Thick
2803-5262	U2 Total Knee System, Tibial Augment Set, Screw Locking, #6, 10mm Thick
2803-5272	U2 Total Knee System, Tibial Augment Set, Screw Locking, #7, 10mm Thick
2803-5113	Tibial augment, screw locking, #1, 15mm, left medial/right lateral
2803-5123	Tibial augment, screw locking, #2, 15mm, left medial/right lateral
2803-5133	Tibial augment, screw locking, #3, 15mm, left medial/right lateral
2803-5143	Tibial augment, screw locking, #4, 15mm, left medial/right lateral
2803-5153	Tibial augment, screw locking, #5, 15mm, left medial/right lateral
2803-5163	Tibial augment, screw locking, #6, 15mm, left medial/right lateral
2803-5173	Tibial augment, screw locking, #7, 15mm, left medial/right lateral
2803-5213	Tibial augment, screw locking, #1, 15mm, right medial/left lateral
2803-5223	Tibial augment, screw locking, #2, 15mm, right medial/left lateral
2803-5233	Tibial augment, screw locking, #3, 15mm, right medial/left lateral
2803-5243	Tibial augment, screw locking, #4, 15mm, right medial/left lateral
2803-5253	Tibial augment, screw locking, #5, 15mm, right medial/left lateral
2803-5263	Tibial augment, screw locking, #6, 15mm, right medial/left lateral

2803-5273	Tibial augment, screw locking, #7, 15mm, right medial/left lateral
2803-5303	Tibial augment, Ti plasma spray, #0, 15mm, left medial/right lateral
2803-5313	Tibial augment, Ti plasma spray, #1, 15mm, left medial/right lateral
2803-5323	Tibial augment, Ti plasma spray, #2, 15mm, left medial/right lateral
2803-5333	Tibial augment, Ti plasma spray, #3, 15mm, left medial/right lateral
2803-5343	Tibial augment, Ti plasma spray, #4, 15mm, left medial/right lateral
2803-5353	Tibial augment, Ti plasma spray, #5, 15mm, left medial/right lateral
2803-5363	Tibial augment, Ti plasma spray, #6, 15mm, left medial/right lateral
2803-5373	Tibial augment, Ti plasma spray, #7, 15mm, left medial/right lateral
2803-5403	Tibial augment, Ti plasma spray, #0, 15mm, right medial/ left lateral
2803-5413	Tibial augment, Ti plasma spray, #1, 15mm, right medial/left latera
2803-5423	Tibial augment, Ti plasma spray, #2, 15mm, right medial/left lateral
2803-5433	Tibial augment, Ti plasma spray, #3, 15mm, right medial/left lateral
2803-5443	Tibial augment, Ti plasma spray, #4, 15mm, right medial/left lateral
2803-5453	Tibial augment, Ti plasma spray, #5, 15mm, right medial/left lateral
2803-5463	Tibial augment, Ti plasma spray, #6, 15mm, right medial/left lateral
2803-5473	Tibial augment, Ti plasma spray, #7, 15mm, right medial/left lateral
2903-1010	U2 Total Knee System, Offset Stem Adapter, PSA, 2mm
2903-1020	U2 Total Knee System, Offset Stem Adapter, PSA, 4mm
2903-1030	U2 Total Knee System, Offset Stem Adapter, PSA, 6mm
2903-3010	U2 Total Knee System, Offset stem adapter, offset 2mm
2903-3020	U2 Total Knee System, Offset stem adapter, offset 4mm
2903-3030	U2 Total Knee System, Offset stem adapter, offset 6mm
2903-1310	U2 Total Knee System, Tibial Screw
2703-5000	U2 Total Knee System, Tibial Plug

2803-7011	Tibial augment, MBA, #1, 5mm
2803-7012	Tibial augment, MBA, #1, 10mm
2803-7021	Tibial augment, MBA, #2, 5mm
2803-7022	Tibial augment, MBA, #2, 10mm
2803-7031	Tibial augment, MBA, #3, 5mm
2803-7032	Tibial augment, MBA, #3, 10mm
2803-7041	Tibial augment, MBA, #4, 5mm
2803-7042	Tibial augment, MBA, #4, 10mm
2803-7051	Tibial augment, MBA, #5, 5mm
2803-7052	Tibial augment, MBA, #5, 10mm
2803-7061	Tibial augment, MBA, #6, 5mm
2803-7062	Tibial augment, MBA, #6, 10mm
2715-5109	Cemented Tibial Stem, Ø9, 20mm
2715-5209	Cemented Tibial Stem, Ø9, 45mm
2715-5309	Cemented Tibial Stem, Ø9, 70mm
2715-5409	Cemented Tibial Stem, Ø9, 95mm
2715-5509	Cemented Tibial Stem, Ø9, 120mm
2715-5609	Cemented Tibial Stem, Ø9, 145mm
2715-7212	Tibial Stem, Ø12.5, 45mm
2715-7214	Tibial Stem, Ø14, 45mm

EC Declaration of Conformity

For the following equipment:

U2 Total Knee System-PSA Type

(Product Name)

UMDNS code : 16-096 Prosthesis, Joint, Knee, Total

GMDN code : 33665 Posterior-stabilized total knee prosthesis

(Model, Designation)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC and 2005/50/EC** with the compliance of conformity assessment Annex II to be certified by British Standards Institution (notify body number – 2797).

For the evaluation regarding the Class III product safety aspects, the following **harmonized standards** are applied:

EN ISO 13485, EN ISO 14630, EN ISO 21534, EN ISO 21536, EN ISO 14971, EN ISO 11137-1, EN ISO 11137-2, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11607-1, EN ISO 11607-2, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-11, EN 1041, EN 556-1, EN ISO 15223-1, EN ISO 22442-1, EN ISO 22442-2, EN ISO 22442-3

The following European Authorized Representative is stated to the declaration:

mdi Europa GmbH / Langenhagener Straße 71, 30855 Langenhagen, Germany

(Company Name/ Address)

This declaration is issued under the sole responsibility of United Orthopaedic Corporation.

The following person is responsible for the compliance of declaration:

United Orthopedic Corporation / No. 57, Park Ave. 2, Science Park, Hsinchu City 30075, Taiwan

(Manufacturer Name/ Address)

Jason Lin / President

(Name/ Position)


(Legal Signature)

2020/07/08

(Date)

Catalog No.	Description
2103-5110	Femoral component, PSA type, #1, left
2103-5120	Femoral component, PSA type, #2, left
2103-5130	Femoral component, PSA type, #3, left
2103-5140	Femoral component, PSA type, #4, left
2103-5150	Femoral component, PSA type, #5, left
2103-5160	Femoral component, PSA type, #6, left
2103-5210	Femoral component, PSA type, #1,Right
2103-5220	Femoral component, PSA type, #2,Right
2103-5230	Femoral component, PSA type, #3,Right
2103-5240	Femoral component, PSA type, #4,Right
2103-5250	Femoral component, PSA type, #5,Right
2103-5260	Femoral component, PSA type, #6,Right
2303-5011	Tibial insert, PSA type, #1, 9mm
2303-5012	Tibial insert, PSA type, #1, 11mm
2303-5013	Tibial insert, PSA type, #1, 13mm
2303-5014	Tibial insert, PSA type, #1, 15mm
2303-5015	Tibial insert, PSA type, #1, 18mm
2303-5016	Tibial insert, PSA type, #1, 21mm
2303-5017	Tibial insert, PSA type, #1, 25mm
2303-5018	Tibial insert, PSA type, #1, 30mm
2303-5021	Tibial insert, PSA type, #2, 9mm
2303-5022	Tibial insert, PSA type, #2, 11mm
2303-5023	Tibial insert, PSA type, #2, 13mm
2303-5024	Tibial insert, PSA type, #2, 15mm
2303-5025	Tibial insert, PSA type, #2, 18mm
2303-5026	Tibial insert, PSA type, #2, 21mm
2303-5027	Tibial insert, PSA type, #2, 25mm
2303-5028	Tibial insert, PSA type, #2, 30mm
2303-5031	Tibial insert, PSA type, #3, 9mm
2303-5032	Tibial insert, PSA type, #3, 11mm
2303-5033	Tibial insert, PSA type, #3, 13mm
2303-5034	Tibial insert, PSA type, #3, 15mm
2303-5035	Tibial insert, PSA type, #3, 18mm
2303-5036	Tibial insert, PSA type, #3, 21mm
2303-5037	Tibial insert, PSA type, #3, 25mm
2303-5038	Tibial insert, PSA type, #3, 30mm
2303-5041	Tibial insert, PSA type, #4, 9mm

Catalog No.	Description
2303-5042	Tibial insert, PSA type, #4, 11mm
2303-5043	Tibial insert, PSA type, #4, 13mm
2303-5044	Tibial insert, PSA type, #4, 15mm
2303-5045	Tibial insert, PSA type, #4, 18mm
2303-5046	Tibial insert, PSA type, #4, 21mm
2303-5047	Tibial insert, PSA type, #4, 25mm
2303-5048	Tibial insert, PSA type, #4, 30mm
2303-5051	Tibial insert, PSA type, #5, 9mm
2303-5052	Tibial insert, PSA type, #5, 11mm
2303-5053	Tibial insert, PSA type, #5, 13mm
2303-5054	Tibial insert, PSA type, #5, 15mm
2303-5055	Tibial insert, PSA type, #5, 18mm
2303-5056	Tibial insert, PSA type, #5, 21mm
2303-5057	Tibial insert, PSA type, #5, 25mm
2303-5058	Tibial insert, PSA type, #5, 30mm
2303-5061	Tibial insert, PSA type, #6, 9mm
2303-5062	Tibial insert, PSA type, #6, 11mm
2303-5063	Tibial insert, PSA type, #6, 13mm
2303-5064	Tibial insert, PSA type, #6, 15mm
2303-5065	Tibial insert, PSA type, #6, 18mm
2303-5066	Tibial insert, PSA type, #6, 21mm
2303-5067	Tibial insert, PSA type, #6, 25mm
2303-5068	Tibial insert, PSA type, #6, 30mm
2203-5010	Tibial Baseplate, PSA type, #1
2203-5020	Tibial Baseplate, PSA type, #2
2203-5030	Tibial Baseplate, PSA type, #3
2203-5040	Tibial Baseplate, PSA type, #4
2203-5050	Tibial Baseplate, PSA type, #5
2203-5060	Tibial Baseplate, PSA type, #6
2203-5210	Tibial Baseplate, PSA type, Screw locking, #1
2203-5220	Tibial Baseplate, PSA type, Screw locking, #2
2203-5230	Tibial Baseplate, PSA type, Screw locking, #3
2203-5240	Tibial Baseplate, PSA type, Screw locking, #4
2203-5250	Tibial Baseplate, PSA type, Screw locking, #5
2203-5260	Tibial Baseplate, PSA type, Screw locking, #6
2703-5003	Straight stem, PSA type, Ø14x30mm
2703-5011	Straight stem, PSA type, Ø10x75mm
2703-5112	Straight stem, PSA type, Ø11x75mm

Catalog No.	Description
2703-5012	Straight stem, PSA type, Ø12x75mm
2703-5113	Straight stem, PSA type, Ø13x75mm
2703-5013	Straight stem, PSA type, Ø14x75mm
2703-5114	Straight stem, PSA type, Ø15x75mm
2703-5014	Straight stem, PSA type, Ø16x75mm
2703-5115	Straight stem, PSA type, Ø17x75mm
2703-5015	Straight stem, PSA type, Ø18x75mm
2703-5116	Straight stem, PSA type, Ø19x75mm
2703-5016	Straight stem, PSA type, Ø20x75mm
2703-5117	Straight stem, PSA type, Ø21x75mm
2703-5017	Straight stem, PSA type, Ø22x75mm
2703-5118	Straight stem, PSA type, Ø23x75mm
2703-5018	Straight stem, PSA type, Ø24x75mm
2703-5021	Straight stem, PSA type, Ø10x100mm
2703-5122	Straight stem, PSA type, Ø11x100mm
2703-5022	Straight stem, PSA type, Ø12x100mm
2703-5123	Straight stem, PSA type, Ø13x100mm
2703-5023	Straight stem, PSA type, Ø14x100mm
2703-5124	Straight stem, PSA type, Ø15x100mm
2703-5024	Straight stem, PSA type, Ø16x100mm
2703-5125	Straight stem, PSA type, Ø17x100mm
2703-5025	Straight stem, PSA type, Ø18x100mm
2703-5126	Straight stem, PSA type, Ø19x100mm
2703-5026	Straight stem, PSA type, Ø20x100mm
2703-5127	Straight stem, PSA type, Ø21x100mm
2703-5027	Straight stem, PSA type, Ø22x100mm
2703-5128	Straight stem, PSA type, Ø23x100mm
2703-5028	Straight stem, PSA type, Ø24x100mm
2703-5051	Straight stem, PSA type, Ø10x150mm
2703-5052	Straight stem, PSA type, Ø12x150mm
2703-5053	Straight stem, PSA type, Ø14x150mm
2703-5054	Straight stem, PSA type, Ø16x150mm
2703-5055	Straight stem, PSA type, Ø18x150mm
2703-5056	Straight stem, PSA type, Ø20x150mm
2703-5057	Straight stem, PSA type, Ø22x150mm
2703-5058	Straight stem, PSA type, Ø24x150mm
2703-5152	Straight stem, PSA type, Ø11x150mm
2703-5153	Straight stem, PSA type, Ø13x150mm

Catalog No.	Description
2703-5154	Straight stem, PSA type, Ø15x150mm
2703-5155	Straight stem, PSA type, Ø17x150mm
2703-5156	Straight stem, PSA type, Ø19x150mm
2703-5157	Straight stem, PSA type, Ø21x150mm
2703-5158	Straight stem, PSA type, Ø23x150mm
2703-5061	Straight stem, PSA type, Ø10x200mm
2703-5062	Straight stem, PSA type, Ø12x200mm
2703-5063	Straight stem, PSA type, Ø14x200mm
2703-5064	Straight stem, PSA type, Ø16x200mm
2703-5065	Straight stem, PSA type, Ø18x200mm
2703-5066	Straight stem, PSA type, Ø20x200mm
2703-5067	Straight stem, PSA type, Ø22x200mm
2703-5068	Straight stem, PSA type, Ø24x200mm
2703-5162	Straight stem, PSA type, Ø11x200mm
2703-5163	Straight stem, PSA type, Ø13x200mm
2703-5164	Straight stem, PSA type, Ø15x200mm
2703-5165	Straight stem, PSA type, Ø17x200mm
2703-5166	Straight stem, PSA type, Ø19x200mm
2703-5167	Straight stem, PSA type, Ø21x200mm
2703-5168	Straight stem, PSA type, Ø23x200mm
2703-5081	Straight stem, PSA type, φ10×240mm
2703-5082	Straight stem, PSA type, φ12×240mm
2703-5083	Straight stem, PSA type, φ14×240mm
2703-5084	Straight stem, PSA type, φ16×240mm
2703-5085	Straight stem, PSA type, φ18×240mm
2703-5086	Straight stem, PSA type, φ20×240mm
2703-5087	Straight stem, PSA type, φ22×240mm
2703-5088	Straight stem, PSA type, φ24×240mm
2703-5182	Straight stem, PSA type, φ11×240mm
2703-5183	Straight stem, PSA type, φ13×240mm
2703-5184	Straight stem, PSA type, φ15×240mm
2703-5185	Straight stem, PSA type, φ17×240mm
2703-5186	Straight stem, PSA type, φ19×240mm
2703-5187	Straight stem, PSA type, φ21×240mm
2703-5188	Straight stem, PSA type, φ23×240mm
2703-5211	Straight stem, PSA type, Cemented, Ø10x75mm
2703-5212	Straight stem, PSA type, Cemented, Ø12x75mm
2703-5213	Straight stem, PSA type, Cemented, Ø14x75mm

Catalog No.	Description
2703-5214	Straight stem, PSA type, Cemented, Ø16x75mm
2703-5215	Straight stem, PSA type, Cemented, Ø18x75mm
2703-5216	Straight stem, PSA type, Cemented, Ø20x75mm
2703-5217	Straight stem, PSA type, Cemented, Ø22x75mm
2703-5221	Straight stem, PSA type, Cemented, Ø10x100mm
2703-5222	Straight stem, PSA type, Cemented, Ø12x100mm
2703-5223	Straight stem, PSA type, Cemented, Ø14x100mm
2703-5224	Straight stem, PSA type, Cemented, Ø16x100mm
2703-5225	Straight stem, PSA type, Cemented, Ø18x100mm
2703-5226	Straight stem, PSA type, Cemented, Ø20x100mm
2703-5227	Straight stem, PSA type, Cemented, Ø22x100mm
2703-5031	Curved stem, PSA type, Ø10x150mm
2703-5132	Curved stem, PSA type, Ø11x150mm
2703-5032	Curved stem, PSA type, Ø12x150mm
2703-5133	Curved stem, PSA type, Ø13x150mm
2703-5033	Curved stem, PSA type, Ø14x150mm
2703-5134	Curved stem, PSA type, Ø15x150mm
2703-5034	Curved stem, PSA type, Ø16x150mm
2703-5135	Curved stem, PSA type, Ø17x150mm
2703-5035	Curved stem, PSA type, Ø18x150mm
2703-5136	Curved stem, PSA type, Ø19x150mm
2703-5036	Curved stem, PSA type, Ø20x150mm
2703-5137	Curved stem, PSA type, Ø21x150mm
2703-5037	Curved stem, PSA type, Ø22x150mm
2703-5138	Curved stem, PSA type, Ø23x150mm
2703-5038	Curved stem, PSA type, Ø24x150mm
2703-5041	Curved stem, PSA type, Ø10x200mm
2703-5142	Curved stem, PSA type, Ø11x200mm
2703-5042	Curved stem, PSA type, Ø12x200mm
2703-5143	Curved stem, PSA type, Ø13x200mm
2703-5043	Curved stem, PSA type, Ø14x200mm
2703-5144	Curved stem, PSA type, Ø15x200mm
2703-5044	Curved stem, PSA type, Ø16x200mm
2703-5145	Curved stem, PSA type, Ø17x200mm
2703-5045	Curved stem, PSA type, Ø18x200mm
2703-5146	Curved stem, PSA type, Ø19x200mm
2703-5046	Curved stem, PSA type, Ø20x200mm
2703-5147	Curved stem, PSA type, Ø21x200mm

Catalog No.	Description
2703-5047	Curved stem, PSA type, Ø22x200mm
2703-5148	Curved stem, PSA type, Ø23x200mm
2703-5048	Curved stem, PSA type, Ø24x200mm
2703-5071	Curved stem, PSA type, Ø10x240mm
2703-5072	Curved stem, PSA type, Ø12x240mm
2703-5073	Curved stem, PSA type, Ø14x240mm
2703-5074	Curved stem, PSA type, Ø16x240mm
2703-5075	Curved stem, PSA type, Ø18x240mm
2703-5076	Curved stem, PSA type, Ø20x240mm
2703-5077	Curved stem, PSA type, Ø22x240mm
2703-5078	Curved stem, PSA type, Ø24x240mm
2703-5172	Curved stem, PSA type, Ø11x240mm
2703-5173	Curved stem, PSA type, Ø13x240mm
2703-5174	Curved stem, PSA type, Ø15x240mm
2703-5175	Curved stem, PSA type, Ø17x240mm
2703-5176	Curved stem, PSA type, Ø19x240mm
2703-5177	Curved stem, PSA type, Ø21x240mm
2703-5178	Curved stem, PSA type, Ø23x240mm
2703-5231	Curved stem, PSA type, Cemented, Ø10x150mm
2703-5232	Curved stem, PSA type, Cemented, Ø12x150mm
2703-5233	Curved stem, PSA type, Cemented, Ø14x150mm
2703-5234	Curved stem, PSA type, Cemented, Ø16x150mm
2703-5235	Curved stem, PSA type, Cemented, Ø18x150mm
2703-5236	Curved stem, PSA type, Cemented, Ø20x150mm
2703-5237	Curved stem, PSA type, Cemented, Ø22x150mm
2703-5241	Curved stem, PSA type, Cemented, Ø10x200mm
2703-5242	Curved stem, PSA type, Cemented, Ø12x200mm
2703-5243	Curved stem, PSA type, Cemented, Ø14x200mm
2703-5244	Curved stem, PSA type, Cemented, Ø16x200mm
2703-5245	Curved stem, PSA type, Cemented, Ø18x200mm
2703-5246	Curved stem, PSA type, Cemented, Ø20x200mm
2703-5247	Curved stem, PSA type, Cemented, Ø22x200mm
2903-1012	Femoral screw, M5x12mm
2903-1014	Femoral screw, M5x14mm
2903-1016	Femoral screw, M5x16mm