

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHHECHISCHE REPUBLIK  
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE  
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

## EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.  
(Annex II of Directive 93/42/EEC)

No.: MED 200057

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer

**BEZNOSKA, s.r.o.**  
**Dělnická 2727, 272 01 Kladno - Kročehlavy, Czech Republic**

for design, manufacturing and final inspection of medical device(s)

**Ancillary components for total knee replacement systém - class IIb, see enclosure**

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **MED000077-05/01 of: 28.04.2020,**

**MED000077-08/01 of: 24.06.2020.**

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 30.06.2020 with validity until 26.05.2024

**The validity of this Certificate is limited until: 26.05.2024**

30.06.2020

Prague

Mgr. Miroslav Sedláček  
Head of Certification Body



\* C E R / H E D 2 0 0 0 5 7 \*

MED000077-05

## Certificate history

Date	Status	Reason
30.06.2020	Issuance	Replacement of certificate No. MED 190039



## Ancillary components for total knee replacement system - class IIb

### AUGMENTATION

Reference	Description
360020	SVR - Distal femoral aug., 2L/LAT-4
360022	SVR - Distal femoral aug., 2L/LAT-10/0
360023	SVR - Distal femoral aug., 2L/LAT-10/4
360024	SVR - Distal femoral aug., 2L/LAT-10/10
360025	SVR - Distal femoral aug., 2L/MED-4
360027	SVR - Distal femoral aug., 2L/MED-10/0
360028	SVR - Distal femoral aug., 2L/MED-10/4
360029	SVR - Distal femoral aug., 2L/MED-10/10
360030	SVR - Distal femoral aug., 3L/LAT-4
360032	SVR - Distal femoral aug., 3L/LAT-10/0
360033	SVR - Distal femoral aug., 3L/LAT-10/4
360034	SVR - Distal femoral aug., 3L/LAT-10/10
360035	SVR - Distal femoral aug., 3L/MED-4
360037	SVR - Distal femoral aug., 3L/MED-10/0
360038	SVR - Distal femoral aug., 3L/MED-10/4
360039	SVR - Distal femoral aug., 3L/MED-10/10
360040	SVR - Distal femoral aug., 4L/LAT-4
360042	SVR - Distal femoral aug., 4L/LAT-10/0
360043	SVR - Distal femoral aug., 4L/LAT-10/4
360044	SVR - Distal femoral aug., 4L/LAT-10/10
360045	SVR - Distal femoral aug., 4L/MED-4
360047	SVR - Distal femoral aug., 4L/MED-10/0
360048	SVR - Distal femoral aug., 4L/MED-10/4
360049	SVR - Distal femoral aug., 4L/MED-10/10
360050	SVR - Distal femoral aug., 5L/LAT-4
360052	SVR - Distal femoral aug., 5L/LAT-10/0
360053	SVR - Distal femoral aug., 5L/LAT-10/4
360054	SVR - Distal femoral aug., 5L/LAT-10/10
360055	SVR - Distal femoral aug., 5L/MED-4
360057	SVR - Distal femoral aug., 5L/MED-10/0
360058	SVR - Distal femoral aug., 5L/MED-10/4
360059	SVR - Distal femoral aug., 5L/MED-10/10
360060	SVR - Distal femoral aug., 6L/LAT-4
360062	SVR - Distal femoral aug., 6L/LAT-10/0
360063	SVR - Distal femoral aug., 6L/LAT-10/4
360064	SVR - Distal femoral aug., 6L/LAT-10/10
360065	SVR - Distal femoral aug., 6L/MED-4
360067	SVR - Distal femoral aug., 6L/MED-10/0
360068	SVR - Distal femoral aug., 6L/MED-10/4
360069	SVR - Distal femoral aug., 6L/MED-10/10
360120	SVR - Dorsal femoral aug., 2, L/LAT, R/MED-4
360122	SVR - Dorsal femoral aug., 2, L/LAT, R/MED-10
360130	SVR - Dorsal femoral aug., 3, L/LAT, R/MED-4
360132	SVR - Dorsal femoral aug., 3, L/LAT, R/MED-10
360140	SVR - Dorsal femoral aug., 4, L/LAT, R/MED-4
360142	SVR - Dorsal femoral aug., 4, L/LAT, R/MED-10
360150	SVR - Dorsal femoral aug., 5, L/LAT, R/MED-4
360152	SVR - Dorsal femoral aug., 5, L/LAT, R/MED-10

*Uhlavice*



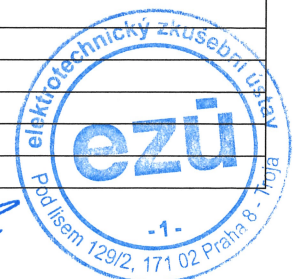
360160	SVR - Dorsal femoral aug., 6, L/LAT, R/MED-4
360162	SVR - Dorsal femoral aug., 6, L/LAT, R/MED-10
360320	SVR - Distal femoral aug., 2R/MED-4
360322	SVR - Distal femoral aug., 2R/MED-10/0
360323	SVR - Distal femoral aug., 2R/MED-10/4
360324	SVR - Distal femoral aug., 2R/MED-10/10
360325	SVR - Distal femoral aug., 2R/LAT-4
360327	SVR - Distal femoral aug., 2R/LAT-10/0
360328	SVR - Distal femoral aug., 2R/LAT-10/4
360329	SVR - Distal femoral aug., 2R/LAT-10/10
360330	SVR - Distal femoral aug., 3R/MED-4
360332	SVR - Distal femoral aug., 3R/MED-10/0
360333	SVR - Distal femoral aug., 3R/MED-10/4
360334	SVR - Distal femoral aug., 3R/MED-10/10
360335	SVR - Distal femoral aug., 3R/LAT-4
360337	SVR - Distal femoral aug., 3R/LAT-10/0
360338	SVR - Distal femoral aug., 3R/LAT-10/4
360339	SVR - Distal femoral aug., 3R/LAT-10/10
360340	SVR - Distal femoral aug., 4R/MED-4
360342	SVR - Distal femoral aug., 4R/MED-10/0
360343	SVR - Distal femoral aug., 4R/MED-10/4
360344	SVR - Distal femoral aug., 4R/MED-10/10
360345	SVR - Distal femoral aug., 4R/LAT-4
360347	SVR - Distal femoral aug., 4R/LAT-10/0
360348	SVR - Distal femoral aug., 4R/LAT-10/4
360349	SVR - Distal femoral aug., 4R/LAT-10/10
360350	SVR - Distal femoral aug., 5R/MED-4
360352	SVR - Distal femoral aug., 5R/MED-10/0
360353	SVR - Distal femoral aug., 5R/MED-10/4
360354	SVR - Distal femoral aug., 5R/MED-10/10
360355	SVR - Distal femoral aug., 5R/LAT-4
360357	SVR - Distal femoral aug., 5R/LAT-10/0
360358	SVR - Distal femoral aug., 5R/LAT-10/4
360359	SVR - Distal femoral aug., 5R/LAT-10/10
360360	SVR - Distal femoral aug., 6R/MED-4
360362	SVR - Distal femoral aug., 6R/MED-10/0
360363	SVR - Distal femoral aug., 6R/MED-10/4
360364	SVR - Distal femoral aug., 6R/MED-10/10
360365	SVR - Distal femoral aug., 6R/LAT-4
360367	SVR - Distal femoral aug., 6R/LAT-10/0
360368	SVR - Distal femoral aug., 6R/LAT-10/4
360369	SVR - Distal femoral aug., 6R/LAT-10/10
360420	SVR - Dorsal femoral aug., 2, L/MED, R/LAT-4
360422	SVR - Dorsal femoral aug., 2, L/MED, R/LAT-10
360430	SVR - Dorsal femoral aug., 3, L/MED, R/LAT-4
360432	SVR - Dorsal femoral aug., 3, L/MED, R/LAT-10
360440	SVR - Dorsal femoral aug., 4, L/MED, R/LAT-4
360442	SVR - Dorsal femoral aug., 4, L/MED, R/LAT-10
360450	SVR - Dorsal femoral aug., 5, L/MED, R/LAT-4
360452	SVR - Dorsal femoral aug., 5, L/MED, R/LAT-10
360460	SVR - Dorsal femoral aug., 6, L/MED, R/LAT-4
360462	SVR - Dorsal femoral aug., 6, L/MED, R/LAT-10
361001	SVR - Shaped tibial aug., 1/L-10
361002	SVR - Shaped tibial aug., 1/L-20
361005	SVR - Shaped tibial aug., 1/R-10
361006	SVR - Shaped tibial aug., 1/R-20

*G. Hlaváč*



361011	SVR - Shaped tibial aug., 2/L-10
361012	SVR - Shaped tibial aug., 2/L-20
361015	SVR - Shaped tibial aug., 2/R-10
361016	SVR - Shaped tibial aug., 2/R-20
361021	SVR - Shaped tibial aug., 3/L-10
361022	SVR - Shaped tibial aug., 3/L-20
361025	SVR - Shaped tibial aug., 3/R-10
361026	SVR - Shaped tibial aug., 3/R-20
361031	SVR - Shaped tibial aug., 4/L-10
361032	SVR - Shaped tibial aug., 4/L-20
361035	SVR - Shaped tibial aug., 4/R-10
361036	SVR - Shaped tibial aug., 4/R-20
361041	SVR - Shaped tibial aug., 5/L-10
361042	SVR - Shaped tibial aug., 5/L-20
361045	SVR - Shaped tibial aug., 5/R-10
361046	SVR - Shaped tibial aug., 5/R-20
361051	SVR - Shaped tibial aug., 6/L-10
361052	SVR - Shaped tibial aug., 6/L-20
361055	SVR - Shaped tibial aug., 6/R-10
361056	SVR - Shaped tibial aug., 6/R-20
361101	SVR - Bevelled tibial aug., 1/L-5
361102	SVR - Bevelled tibial aug., 1/L-10
361105	SVR - Bevelled tibial aug., 1/R-5
361106	SVR - Bevelled tibial aug., 1/R-10
361111	SVR - Bevelled tibial aug., 2/L-5
361112	SVR - Bevelled tibial aug., 2/L-10
361115	SVR - Bevelled tibial aug., 2/R-5
361116	SVR - Bevelled tibial aug., 2/R-10
361121	SVR - Bevelled tibial aug., 3/L-5
361122	SVR - Bevelled tibial aug., 3/L-10
361125	SVR - Bevelled tibial aug., 3/R-5
361126	SVR - Bevelled tibial aug., 3/R-10
361131	SVR - Bevelled tibial aug., 4/L-5
361132	SVR - Bevelled tibial aug., 4/L-10
361135	SVR - Bevelled tibial aug., 4/R-5
361136	SVR - Bevelled tibial aug., 4/R-10
361141	SVR - Bevelled tibial aug., 5/L-5
361142	SVR - Bevelled tibial aug., 5/L-10
361145	SVR - Bevelled tibial aug., 5/R-5
361146	SVR - Bevelled tibial aug., 5/R-10
361151	SVR - Bevelled tibial aug., 6/L-5
361152	SVR - Bevelled tibial aug., 6/L-10
361155	SVR - Bevelled tibial aug., 6/R-5
361156	SVR - Bevelled tibial aug., 6/R-10
361201	SVR - Block tibial aug., 1/L-8
361202	SVR - Block tibial aug., 1/L-15
361205	SVR - Block tibial aug., 1/R-8
361206	SVR - Block tibial aug., 1/R-15
361211	SVR - Block tibial aug., 2/L-8
361212	SVR - Block tibial aug., 2/L-15
361215	SVR - Block tibial aug., 2/R-8
361216	SVR - Block tibial aug., 2/R-15
361221	SVR - Block tibial aug., 3/L-8
361222	SVR - Block tibial aug., 3/L-15
361225	SVR - Block tibial aug., 3/R-8
361226	SVR - Block tibial aug., 3/R-15

*G. Hlavicek*



361231	SVR - Block tibial aug., 4/L-8
361232	SVR - Block tibial aug., 4/L-15
361235	SVR - Block tibial aug., 4/R-8
361236	SVR - Block tibial aug., 4/R-15
361241	SVR - Block tibial aug., 5/L-8
361242	SVR - Block tibial aug., 5/L-15
361245	SVR - Block tibial aug., 5/R-8
361246	SVR - Block tibial aug., 5/R-15
361251	SVR - Block tibial aug., 6/L-8
361252	SVR - Block tibial aug., 6/L-15
361255	SVR - Block tibial aug., 6/R-8
361256	SVR - Block tibial aug., 6/R-15

**FITTING**

Reference	Description
360550	SVR - Femoral coupler, I/5
360552	SVR - Femoral coupler, I/7
360560	SVR - Femoral coupler, II/5
360562	SVR - Femoral coupler, II/7

**STEM**

Reference	Description
360610	SVR - Cementless femoral stem, D12, L120
360612	SVR - Cementless femoral stem, D12, L180
360620	SVR - Cementless femoral stem, D14, L120
360622	SVR - Cementless femoral stem, D14, L180
360630	SVR - Cementless femoral stem, D16, L120
360632	SVR - Cementless femoral stem, D16, L180
360640	SVR - Cementless femoral stem, D18, L120
360642	SVR - Cementless femoral stem, D18, L180
360650	SVR - Cementless femoral stem, D20, L120
360652	SVR - Cementless femoral stem, D20, L180
360660	SVR - Cementless femoral stem, D22, L120
360662	SVR - Cementless femoral stem, D22, L180
360900	SVR - Cementless tibial stem, D10, L80
360901	SVR - Cementless tibial stem, D10, L50
360902	SVR - Cementless tibial stem, D10, L120
360904	SVR - Cementless tibial stem, D10, L180
360909	SVR - Cementless tibial stem, D12, L50
360910	SVR - Cementless tibial stem, D12, L80
360912	SVR - Cementless tibial stem, D12, L120
360914	SVR - Cementless tibial stem, D12, L180
360919	SVR - Cementless tibial stem, D14, L50
360920	SVR - Cementless tibial stem, D14, L80
360922	SVR - Cementless tibial stem, D14, L120
360924	SVR - Cementless tibial stem, D14, L180
360929	SVR - Cementless tibial stem, D16, L50
360930	SVR - Cementless tibial stem, D16, L80
360932	SVR - Cementless tibial stem, D16, L120
360934	SVR - Cementless tibial stem, D16, L180
360939	SVR - Cementless tibial stem, D18, L50
360940	SVR - Cementless tibial stem, D18, L80
360942	SVR - Cementless tibial stem, D18, L120
360944	SVR - Cementless tibial stem, D18, L180
360949	SVR - Cementless tibial stem, D20, L50



360950	SVR - Cementless tibial stem, D20, L80
360952	SVR - Cementless tibial stem, D20, L120
360954	SVR - Cementless tibial stem, D20, L180
360970	SVL - Tibial plateau stem plug, Ti
360971	SVL - Tibial cemented stem, D12, L25
360972	SVL - Tibial cemented stem, D12, L50
360975	SVL - Tibial cemented stem, D15, L25
360976	SVL - Tibial cemented stem, D15, L50
360980	SVL - Stem plug for tibial plateau, PMMA

**ANCILLARY COMPONENTS SVR II**

Reference	Description
360202	SVR II - Metaphyseal femoral aug., F1
360203	SVR II - Metaphyseal femoral aug., F2
360204	SVR II - Metaphyseal femoral aug., F3
360205	SVR II - Metaphyseal femoral aug., F4
360206	SVR II - Metaphyseal femoral aug., F5
360221	SVR II - Coupling stem for femoral metaphyseal aug., L150
360222	SVR II - Coupling stem for femoral metaphyseal aug., L210
360231	SVR II - Stem for metaphyseal femoral aug. D12, L150
360235	SVR II - Stem for metaphyseal femoral aug. D12, L210
360241	SVR II - Stem for metaphyseal femoral aug. D14, L150
360245	SVR II - Stem for metaphyseal femoral aug. D14, L210
360251	SVR II - Stem for metaphyseal femoral aug. D16, L150
360255	SVR II - Stem for metaphyseal femoral aug. D16, L210
360261	SVR II - Sleeve for metaphyseal coupling stem, D14, L55
360265	SVR II - Sleeve for metaphyseal coupling stem, D16, L55
360271	SVR II - Sleeve for metaphyseal coupling stem, D18, L55
360275	SVR II - Sleeve for metaphyseal coupling stem, D20, L55
360281	SVR II - Sleeve for metaphyseal coupling stem, D22, L55
360791	SVR II - Offset, I/0
360792	SVR II - Offset, I/3
360793	SVR II - Offset, I/6
360979	SVR II - Stem plug for metaphyseal tibial aug.
360981	SVR II - Stem for metaphyseal tibial aug., D10, L100
360982	SVR II - Stem for metaphyseal tibial aug., D10, L120
360983	SVR II - Stem for metaphyseal tibial aug., D10, L150
360986	SVR II - Stem for metaphyseal tibial aug., D12, L100
360987	SVR II - Stem for metaphyseal tibial aug., D12, L120
360988	SVR II - Stem for metaphyseal tibial aug., D12, L150
360991	SVR II - Stem for metaphyseal tibial aug., D14, L100
360992	SVR II - Stem for metaphyseal tibial aug., D14, L120
360993	SVR II - Stem for metaphyseal tibial aug., D14, L150
360996	SVR II - Stem for metaphyseal tibial aug., D16, L100
360997	SVR II - Stem for metaphyseal tibial aug., D16, L120
360998	SVR II - Stem for metaphyseal tibial aug., D16, L150
361061	SVR II - Metaphyseal tibial aug., 1A
361062	SVR II - Metaphyseal tibial aug., 2A
361063	SVR II - Metaphyseal tibial aug., 3A
361064	SVR II - Metaphyseal tibial aug., 4A
361071	SVR II - Metaphyseal tibial aug., 1B
361072	SVR II - Metaphyseal tibial aug., 2B
361073	SVR II - Metaphyseal tibial aug., 3B
361074	SVR II - Metaphyseal tibial aug., 4B

End of list

