

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE 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 200058

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)

**Hip joint replacement (hemiarthroplasty and ancillary components) - 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. **MED000077-04/01 of: 29.04.2020,**

**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



MED000077-04

## Certificate history

Date	Status	Reason
30.06.2020	Issuance	Replacement of certificate No. MED 190038



## Hip joint replacement (hemiarthroplasty and ancillary components) - class IIb

### CEMENTED HIP JOINT REPLACEMENT HEMIARTHROPLASTY

Reference	Designation
314900	Beznoska - Stem CEP, D38
315000	Beznoska - Stem CEP, D40
315100	Beznoska - Stem CEP, D42
315200	Beznoska - Stem CEP, D44
315300	Beznoska - Stem CEP, D46
315400	Beznoska - Stem CEP, D48
315500	Beznoska - Stem CEP, D50
315600	Beznoska - Stem CEP, D52
315700	Beznoska - Stem CEP, D54
315800	Beznoska - Stem CEP, D56
315902	CSB – Stem CEP, D40
315904	CSB – Stem CEP, D42
315906	CSB – Stem CEP, D44
315908	CSB – Stem CEP, D46
315910	CSB – Stem CEP, D48
315912	CSB – Stem CEP, D50
315914	CSB – Stem CEP, D52
315916	CSB – Stem CEP, D54
315918	CSB – Stem CEP, D56
317032	CSB - Stem, 12/14

### ACETABULAR REINFORCEMENTS

Reference	Designation
333560	Reconstruction cage, D46, II/A
333562	Reconstruction cage, D52, II/A
333564	Reconstruction cage, D56, II/A
333570	Reconstruction cage, D46, II/B
333572	Reconstruction cage, D52, II/B
333574	Reconstruction cage, D56, II/B
333600	BS - Reconstruction cage, D51/44 L
333601	BS - Reconstruction cage, D51/44 R
333610	BS - Reconstruction cage, D56/49 L
333611	BS - Reconstruction cage, D56/49 R

### METALLIC HEAD CEP

Reference	Designation
324600	Metal head, 12/14, D38
324602	Metal head, 12/14, D40
324604	Metal head, 12/14, D42
324606	Metal head, 12/14, D44
324608	Metal head, 12/14, D46
324610	Metal head, 12/14, D48
324612	Metal head, 12/14, D50
324614	Metal head, 12/14, D52
324616	Metal head, 12/14, D54
324618	Metal head, 12/14, D56

*U. Klavík*



**Bi-POLAR HEAD CEP**

Reference	Designation
324915	Bi-articular head, 12/14, D42, S
324920	Bi-articular head, 12/14, D44, S
324925	Bi-articular head, 12/14, D46, S
324930	Bi-articular head, 12/14, D48, S
324935	Bi-articular head, 12/14, D50, S
324940	Bi-articular head, 12/14, D52, S
324945	Bi-articular head, 12/14, D54, S
324950	Bi-articular head, 12/14, D56, S

**PLUG UNDER CEMENTED STEM**

Reference	Designation
316000	Plug under cemented stem, D8
316002	Plug under cemented stem, D10
316004	Plug under cemented stem, D12
316006	Plug under cemented stem, D14
316008	Plug under cemented stem, D16
316010	Plug under cemented stem, D18

**ANCILLARY COMPONENTS**

Reference	Designation
119025	Cortical screw, D4.5, L25, short head
119030	Cortical screw, D4.5, L30, short head
119035	Cortical screw, D4.5, L35, short head
119040	Cortical screw, D4.5, L40, short head
119045	Cortical screw, D4.5, L45, short head
119125	Cancellous screw, D6.5, L25, short head
119130	Cancellous screw, D6.5, L30, short head
119135	Cancellous screw, D6.5, L35, short head
119140	Cancellous screw, D6.5, L40, short head
119145	Cancellous screw, D6.5, L45, short head
317011	CSC - Centralizer, 1, D11
317012	CSC - Centralizer, 2, D13
317013	CSC - Centralizer, 3, D15
317014	CSC - Centralizer, 4, D17
317015	CSC - Centralizer, 5, D19
317019	Trio - Centralizer, 01, PMMA
317020	Trio - Centralizer, 0, PMMA
317021	Trio - Centralizer, 1, PMMA
317022	Trio - Centralizer, 2, PMMA
317023	Trio - Centralizer, 3, PMMA
317024	Trio - Centralizer, 4, PMMA
317025	Trio - Centralizer, 5, PMMA
317026	Trio - Centralizer, 6, PMMA
317027	Trio - Centralizer, 7, PMMA
317028	Trio - Centralizer, 8, PMMA
331906	SF - Cortical screw, D4.5, L15
331908	SF - Cortical screw, D4.5, L20
331910	SF - Cortical screw, D4.5, L25
331912	SF - Cortical screw, D4.5, L30
331914	SF - Cortical screw, D4.5, L35
331916	SF - Cortical screw, D4.5, L40
331918	SF - Cortical screw, D4.5, L45
331922	SF - Cortical screw, D4.5, L55

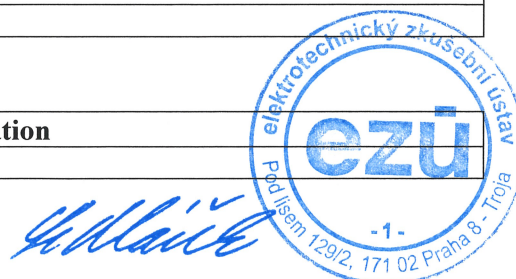


*J. Mařík*

331930	DUO - Cortical screw, D4.5, L15
331931	DUO - Cortical screw, D4.5, L20
331932	DUO - Cortical screw, D4.5, L25
331933	DUO - Cortical screw, D4.5, L30
331934	DUO - Cortical screw, D4.5, L35
331935	DUO - Cortical screw, D4.5, L40
331936	DUO - Cortical screw, D4.5, L45
331937	DUO - Cortical screw, D4.5, L55
331940	DUO - Cancellous screw, D6.5, L20
331941	DUO - Cancellous screw, D6.5, L25
331942	DUO - Cancellous screw, D6.5, L30
331943	DUO - Cancellous screw, D6.5, L35
331944	DUO - Cancellous screw, D6.5, L40
331945	DUO - Cancellous screw, D6.5, L45
331946	DUO - Cancellous screw, D6.5, L55
331948	SF - Cancellous screw, D6.5, L20
331950	SF - Cancellous screw, D6.5, L25
331952	SF - Cancellous screw, D6.5, L30
331954	SF - Cancellous screw, D6.5, L35
331956	SF - Cancellous screw, D6.5, L40
331958	SF - Cancellous screw, D6.5, L45
331962	SF - Cancellous screw, D6.5, L55
331970	TC/II - Screw with angular stability, D4.5, L25
331972	TC/II - Screw with angular stability, D4.5, L30
331974	TC/II - Screw with angular stability, D4.5, L35
331976	TC/II - Screw with angular stability, D4.5, L40
331978	TC/II - Screw with angular stability, D4.5, L45
331980	TC/II - Screw with angular stability, D4.5, L55
333840	TC/II - Distal hook, S
333842	TC/II - Distal hook, L
340400	Distance ring for oncological endoprostheses
343010	Femoral stem collar, S4, B10
343020	Femoral stem collar, S6, B10
343030	Femoral stem collar, S8, B10
343040	Femoral stem collar, S10, B10
343110	Femoral stem collar, S4, B11,5
343120	Femoral stem collar, S6, B11,5
343130	Femoral stem collar, S8, B11,5
343140	Femoral stem collar, S10, B11,5
343210	Femoral stem collar, S4, B13
343220	Femoral stem collar, S6, B13
343230	Femoral stem collar, S8, B13
343240	Femoral stem collar, S10, B13
343310	Femoral stem collar, S4, B14,5
343320	Femoral stem collar, S6, B14,5
343330	Femoral stem collar, S8, B14,5
343340	Femoral stem collar, S10, B14,5
410000	Cerclage - Cerclage tape
410010	Cerclage - Slider with pikes
410020	Cerclage - Plate, L170
410022	Cerclage - Plate, L200
410024	Cerclage - Plate, L230

**NON STERILE IMPLANTS**

Reference	Designation
711800	K-wire, D1.2, L100 - Triangular tip



711805	K-wire, D1.2, L160 - Triangular tip
711810	K-wire, D1.6, L160 - Triangular tip
711813	K-wire, D1.8, L160 - Triangular tip
711815	K-wire, D2, L160 - Triangular tip
711850	K-wire, D3, L200 - Triangular tip
711855	K-wire, D1.2, L300 - Triangular tip
711860	K-wire, D1.6, L300 - Triangular tip
711863	K-wire, D1.8, L300 - Triangular tip
711865	K-wire, D2, L300 - Triangular tip
711870	K-wire, D2.5, L300 - Triangular tip
711875	K-wire, D3, L300 - Triangular tip
711905	K-wire, D1.2, L160 - Pike tip
711910	K-wire, D1.6, L160 - Pike tip
711913	K-wire, D1.8, L160 - Pike tip
711915	K-wire, D2, L160 - Pike tip
711955	K-wire, D1.2, L300 - Pike tip
711960	K-wire, D1.6, L300 - Pike tip
711963	K-wire, D1.8, L300 - Pike tip
711965	K-wire, D2, L300 - Pike tip
711970	K-wire, D2.5, L300 - Pike tip
711975	K-wire, D3, L300 - Pike tip
910005	Osteofix wire, D0.5, L5 M
910006	Osteofix wire, D0.6, L5 M
910007	Osteofix wire, D0.7, L5 M
910008	Osteofix wire, D0.8, L5 M
910010	Osteofix wire, D1, L5 M
910012	Osteofix wire, D1.2, L5 M

End of list