



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDRTD-005

BEZNOSKA, s.r.o.

Dělnická 2727, Kročehlavy, 272 01 Kladno, Czech Republic

SRN No.: CZ – MF - 000000543

This EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that technical documentation of the medical device:

**REPLACEMENT OF PART OF THE UPPER LIMB -
Replacement of Trapeziometacarpal Joint**

Model: ELIS

TYPE: T

For details, see Annex I

Intended purpose: see Annex II

MD class III, Rule 8

Basic UDI-DI: 852260207001FZ

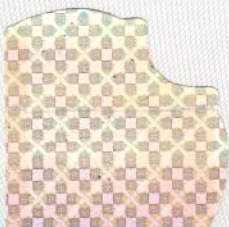
(detailed list is stated in the annex(es) if applicable)

meets the requirements of technical documentation assessment according to the Chapter II Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed technical documentation assessment of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR061_2022 F18A NR from 15.03.2023, MD Clinical Evaluation Report No. MDR061_2022 F21A NR from 15.03.2023 and MD Audit Report No. MDR061_2022 from 30.03.2023. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Technical Documentation Assessment Certificate** applies only to the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **12.05.2023**
Valid until: **12.05.2028**
First issue: **12.05.2023**
Revision: **0**
History: **First issue**

At Bratislava, Slovakia, 12.05.2023



3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265



**ANNEX I TO EU TECHNICAL DOCUMENTATION
ASSESSMENT CERTIFICATE No. 2023-MDR/TD-005**

issued for the company

BEZNOSKA, s.r.o.

Dělnická 2727, Kročehlavy, 272 01 Kladno, Czech Republic

List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Type No.	Trade Name	Other Trade Names
413001	ELiS - Cementless stem, T, 1	
413002	ELiS - Cementless stem, T, 2	
413003	ELiS - Cementless stem, T, 3	
413004	ELiS - Cementless stem, T, 4	
413005	ELiS - Cementless stem, T, 5	
413011	ELiS - Cementless stem, T/II (Ti+HA), 1	
413012	ELiS - Cementless stem, T/II (Ti+HA), 2	
413013	ELiS - Cementless stem, T/II (Ti+HA), 3	
413014	ELiS - Cementless stem, T/II (Ti+HA), 4	
413015	ELiS - Cementless stem, T/II (Ti+HA), 5	
413072	ELiS - Straight neck, T/II, 5/12, S	
413073	ELiS - Straight neck, T/II, 5/14, M	
413074	ELiS - Straight neck, T/II, 5/16, L	
413075	ELiS - Straight neck, T/II, 5/18, XL	
413077	ELiS - Valgus neck 15°, T/II, 5/12, S	
413078	ELiS - Valgus neck 15°, T/II, 5/14, M	

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Katarína Tomin Srdošová, PhD.
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List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Type No.	Trade Name	Other Trade Names
413079	ELiS - Valgus neck 15°, T/II, 5/16, L	
413080	ELiS - Valgus neck 15°, T/II, 5/18, XL	
413082	ELiS - Cemented cup with offset, T/II, 5/10	
413171	ELiS - Cementless cup, T/III, D9	
413172	ELiS - Cementless cup, T/III, D10	
413175	ELiS - Insert, T/III, for head D5	
413180	ELiS - Trapezium repl., TR, 14/15, D9	
413181	ELiS - Trapezium repl., TR, 15/16, D10	
413182	ELiS - Trapezium repl., TR, 16/17, D11	
413190	ELiS - Trapezium insert, TR, 9/5	
413191	ELiS - Trapezium insert, TR, 10/5	
413192	ELiS - Trapezium insert, TR, 11/5	
413021	ELiS - Cementless stem, (CC), 1	
413022	ELiS - Cementless stem, (CC), 2	
413023	ELiS - Cementless stem, (CC), 3	
413024	ELiS - Cementless stem, (CC), 4	

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Type No.	Trade Name	Other Trade Names
413025	ELiS - Cementless stem, (CC), 5	
413026	ELiS - Cementless stem, (CC), 1+	
413027	ELiS - Cementless stem, (CC), 2+	
413028	ELiS - Cementless stem, (CC), 5+	
413054	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/12	
413055	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/14	
413056	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/16	
413057	ELiS - DM - Valgus neck 15°/Ante-L, 7.7/18	
413058	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/12	
413059	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/14	
413060	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/16	
413061	ELiS - DM - Valgus neck 15°/Ante-R, 7.7/18	
413062	ELiS - DM - Straight neck, 7.7/12	
413063	ELiS - DM - Straight neck, 7.7/14	
413064	ELiS - DM - Straight neck, 7.7/16	
413065	ELiS - DM - Straight neck, 7.7/18	

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BEZNOSKA, s.r.o.

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List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Type No.	Trade Name	Other Trade Names
413067	ELIS - DM - Valgus neck 15°, 7.7/12	
413068	ELIS - DM - Valgus neck 15°, 7.7/14	
413069	ELIS - DM - Valgus neck 15°, 7.7/16	
413070	ELIS - DM - Valgus neck 15°, 7.7/18	
413087	ELIS - Valgus neck 15°/Ante-R, 5/12	
413088	ELIS - Valgus neck 15°/Ante-R, 5/14	
413089	ELIS - Valgus neck 15°/Ante-R, 5/16	
413090	ELIS - Valgus neck 15°/Ante-R, 5/18	
413092	ELIS - Sphere - Cemented cup, 5/10	
413097	ELIS - Valgus neck 15°/Ante-L, 5/12	
413098	ELIS - Valgus neck 15°/Ante-L, 5/14	
413099	ELIS - Valgus neck 15°/Ante-L, 5/16	
413100	ELIS - Valgus neck 15°/Ante-L, 5/18	
413173	ELIS - Sphere - Cementless cup (CC), D9	
413174	ELIS - Sphere - Cementless cup (CC), D10	
413176	ELIS - Sphere, DM - Cementless cup (CC), D9	

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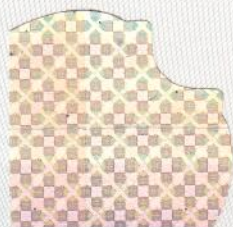
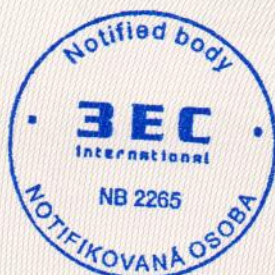
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Dělnická 2727, Kročehlavy, 272 01 Kladno, Czech Republic

List of medical devices covered by the EU Technical Documentation Assessment Certificate:

Type No.	Trade Name	Other Trade Names
413177	ELIS - Sphere, DM - Cementless cup (CC), D10	
413178	ELIS - Konos, DM - Cementless cup (CC), D9	
413179	ELIS - Konos, DM - Cementless cup (CC), D10	

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ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-005

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Intended purpose of medical devices covered by the EU Technical Documentation Assessment Certificate:

Implants are designed to replace the trapeziometacarpal joint.

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ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-005

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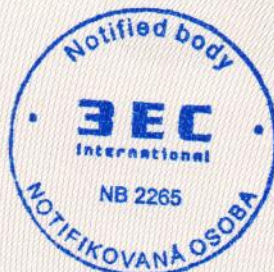
BEZNOSKA, s.r.o.

Dělnická 2727, Kročehlavy, 272 01 Kladno, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
0	2023-MDR/TD-005	12.05.2023	MDR061_2022	Initial issue

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