Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland; Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2022-07-06

CERTIFICATE OF FREE SALE No. 410 / 2022

President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products based on Article 60 of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 z 5.5.2017, p. 1) pursuant to art. 30 of the Act of April 7, 2022 on medical devices (Journal of Laws of 2022, items 974) in connection with the application for a certificate of free sale made by the

POLDENT Sp. z o.o.
(*applicant for certificate of free sale*)

certifies that the medical device listed below :

Name of the device	Type
Endostar K-Files	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261KFHC7

manufactured by :

POLDENT Sp. z o.o.
Ul. Dzika 2, 00-194 Warszawa, Poland
(*identification of the manufacturer*)

on the basis of the statement of the manufacturer is CE marked at the sole responsibility of the manufacturer. The medical device CE marked in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council can be placed on the market and put into service in the European Union. Export of the product is not prohibited.

PREZES URZĘDU REJESTRACJI PRODUKTÓW LECZNICZYCH I PRODUKTÓW BIOBÓJCZYCH WYROBÓW MEDYCZNYCH

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

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Attachment to the Free Sale Certificate number 410/2022 from 06.07.2022

TRADE NAME OF DEVICE: Endostar K-Files

Available codes of instruments:

ISO	code				
	21 mm	25 mm	28 mm	31 mm	35mm
6	EKFH000621 BKFH000621	EKFH000625 BKFH000625	EKFH000628 BKFH000628	EKFH000631 BKFH000631	EKFH000635
8	EKFH000821 BKFH000821	EKFH000825 BKFH000825	EKFH000828 BKFH000828	EKFH000831 BKFH000831	EKFH000835
10	EKFH001021 BKFH001021	EKFH001025 BKFH001025	EKFH001028 BKFH001028	EKFH001031 BKFH001031	EKFH001035
15	EKFH001521 BKFH001521	EKFH001525 BKFH001525	EKFH001528 BKFH001528	EKFH001531 BKFH001531	EKFH001535
20	EKFH002021 BKFH002021	EKFH002025 BKFH002025	EKFH002028 BKFH002028	EKFH002031 BKFH002031	EKFH002035
25	EKFH002521 BKFH002521	EKFH002525 BKFH002525	EKFH002528 BKFH002528	EKFH002531 BKFH002531	EKFH002535
30	EKFH003021 BKFH003021	EKFH003025 BKFH003025	EKFH003028 BKFH003028	EKFH003031 BKFH003031	EKFH003035
35	EKFH003521 BKFH003521	EKFH003525 BKFH003525	EKFH003528 BKFH003528	EKFH003531 BKFH003531	EKFH003535
40	EKFH004021 BKFH004021	EKFH004025 BKFH004025	EKFH004028 BKFH004028	EKFH004031 BKFH004031	EKFH004035
45	EKFH004521 BKFH004521	EKFH004525 BKFH004525	EKFH004528 BKFH004528	EKFH004531 BKFH004531	EKFH004535
50	EKFH005021 BKFH005021	EKFH005025 BKFH005025	EKFH005028 BKFH005028	EKFH005031 BKFH005031	EKFH005035
55	EKFH005521 BKFH005521	EKFH005525 BKFH005525	EKFH005528 BKFH005528	EKFH005531 BKFH005531	EKFH005535
60	EKFH006021 BKFH006021	EKFH006025 BKFH006025	EKFH006028 BKFH006028	EKFH006031 BKFH006031	EKFH006035
70	EKFH007021 BKFH007021	EKFH007025 BKFH007025	EKFH007028 BKFH007028	EKFH007031 BKFH007031	EKFH007035
80	EKFH008021 BKFH008021	EKFH008025 BKFH008025	EKFH008028 BKFH008028	EKFH008031 BKFH008031	EKFH008035
90	EKFH009021 BKFH009021	EKFH009025 BKFH009025	EKFH009028 BKFH009028	EKFH009031 BKFH009031	-
100	EKFH010021 BKFH010021	EKFH010025 BKFH010025	EKFH010028 BKFH010028	EKFH010031 BKFH010031	-
110	EKFH011021 BKFH011021	EKFH011025 BKFH011025	EKFH011028 BKFH011028	EKFH011031 BKFH011031	-
120	EKFH012021 BKFH012021	EKFH012025 BKFH012025	EKFH012028 BKFH012028	EKFH012031 BKFH012031	-
130	EKFH013021 BKFH013021	EKFH013025 BKFH013025	EKFH013028 BKFH013028	EKFH013031 BKFH013031	-

140	EKFH014021 BKFH014021	EKFH014025 BKFH014025	EKFH014028 BKFH014028	EKFH014031 BKFH014031	-
15-40	EKFH154021 BKFH154021	EKFH154025 BKFH154025	EKFH154028 BKFH154028	EKFH154031 BKFH154031	EKFH154035
45-80	EKFH458021 BKFH458021	EKFH458025 BKFH458025	EKFH458028 BKFH458028	EKFH458031 BKFH458031	EKFH458035
90-140	EKFH901421 BKFH901421	EKFH901425 BKFH901425	EKFH901428 BKFH901428	EKFH901431 BKFH901431	-
06-10	EKFH061021	EKFH061025	EKFH061028	EKFH061031	-
15-25	EKFH152521	EKFH152525	EKFH152528	EKFH152531	-

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski