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. 409 / 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 S-Files	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261SFHDF

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 409/2022 from 06.07.2022

TRADE NAME OF DEVICE: Endostar S-Files

Available codes of instruments:

ISO	code			
	21 mm	25 mm	28 mm	31 mm
6	ESFH000621 BSFH000621	ESFH000625 BSFH000625	ESFH000628 BSFH000628	ESFH000631 BSFH000631
8	ESFH000821 BSFH000821	ESFH000825 BSFH000825	ESFH000828 BSFH000828	ESFH000831 BSFH000831
10	ESFH001021 BSFH001021	ESFH001025 BSFH001025	ESFH001028 BSFH001028	ESFH001031 BSFH001031
15	ESFH001521 BSFH001521	ESFH001525 BSFH001525	ESFH001528 BSFH001528	ESFH001531 BSFH001531
20	ESFH002021 BSFH002021	ESFH002025 BSFH002025	ESFH002028 BSFH002028	ESFH002031 BSFH002031
25	ESFH002521 BSFH002521	ESFH002525 BSFH002525	ESFH002528 BSFH002528	ESFH002531 BSFH002531
30	ESFH003021 BSFH003021	ESFH003025 BSFH003025	ESFH003028 BSFH003028	ESFH003031 BSFH003031
35	ESFH003521 BSFH003521	ESFH003525 BSFH003525	ESFH003528 BSFH003528	ESFH003531 BSFH003531
40	ESFH004021 BSFH004021	ESFH004025 BSFH004025	ESFH004028 BSFH004028	ESFH004031 BSFH004031
45	ESFH004521 BSFH004521	ESFH004525 BSFH004525	ESFH004528 BSFH004528	ESFH004531 BSFH004531
50	ESFH005021 BSFH005021	ESFH005025 BSFH005025	ESFH005028 BSFH005028	ESFH005031 BSFH005031
55	ESFH005521 BSFH005521	ESFH005525 BSFH005525	ESFH005528 BSFH005528	ESFH005531 BSFH005531
60	ESFH006021 BSFH006021	ESFH006025 BSFH006025	ESFH006028 BSFH006028	ESFH006031 BSFH006031
70	ESFH007021 BSFH007021	ESFH007025 BSFH007025	ESFH007028 BSFH007028	ESFH007031 BSFH007031
80	ESFH008021 BSFH008021	ESFH008025 BSFH008025	ESFH008028 BSFH008028	ESFH008031 BSFH008031
90	ESFH009021 BSFH009021	ESFH009025 BSFH009025	ESFH009028 BSFH009028	ESFH009031 BSFH009031
100	ESFH010021 BSFH010021	ESFH010025 BSFH010025	ESFH010028 BSFH010028	ESFH010031 BSFH010031
110	ESFH011021 BSFH011021	ESFH011025 BSFH011025	ESFH011028 BSFH011028	ESFH011031 BSFH011031
120	ESFH012021 BSFH012021	ESFH012025 BSFH012025	ESFH012028 BSFH012028	ESFH012031 BSFH012031
130	ESFH013021 BSFH013021	ESFH013025 BSFH013025	ESFH013028 BSFH013028	ESFH013031 BSFH013031

140	ESFH014021 BSFH014021	ESFH014025 BSFH014025	ESFH014028 BSFH014028	ESFH014031 BSFH014031
15-40	ESFH154021 BSFH154021	ESFH154025 BSFH154025	ESFH154028 BSFH154028	ESFH154031 BSFH154031
45-80	ESFH458021 BSFH458021	ESFH458025 BSFH458025	ESFH458028 BSFH458028	ESFH458031 BSFH458031
90-140	ESFH901421 BSFH901421	ESFH901425 BSFH901425	ESFH901428 BSFH901428	ESFH901431 BSFH901431
06-10	-	ESFH061025	-	-
10-15	ESFH101521	ESFH101525	-	-

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski