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. 411 / 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 H-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.

URZĘDU REJESTRACJI PRODUKTÓW LECZNICZYCH I PRODUKTÓW BIOBÓJCZYCH WYROBÓW MEDYCZNYCH * 2 *

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 411/2022 from 06.07.2022

TRADE NAME OF DEVICE: Endostar H-Files

Available codes of instruments:

ISO	code			
	21 mm	25 mm	28 mm	31 mm
6	EHFH000621 BHFH000621	EHFH000625 BHFH000625	EHFH000628 BHFH000628	EHFH000631 BHFH000631
8	EHFH000821 BHFH000821	EHFH000825 BHFH000825	EHFH000828 BHFH000828	EHFH000831 BHFH000831
10	EHFH001021 BHFH001021	EHFH001025 BHFH001025	EHFH001028 BHFH001028	EHFH001031 BHFH001031
15	EHFH001521 BHFH001521	EHFH001525 BHFH001525	EHFH001528 BHFH001528	EHFH001531 BHFH001531
20	EHFH002021 BHFH002021	EHFH002025 BHFH002025	EHFH002028 BHFH002028	EHFH002031 BHFH002031
25	EHFH002521 BHFH002521	EHFH002525 BHFH002525	EHFH002528 BHFH002528	EHFH002531 BHFH002531
30	EHFH003021 BHFH003021	EHFH003025 BHFH003025	EHFH003028 BHFH003028	EHFH003031 BHFH003031
35	EHFH003521 BHFH003521	EHFH003525 BHFH003525	EHFH003528 BHFH003528	EHFH003531 BHFH003531
40	EHFH004021 BHFH004021	EHFH004025 BHFH004025	EHFH004028 BHFH004028	EHFH004031 BHFH004031
45	EHFH004521 BHFH004521	EHFH004525 BHFH004525	EHFH004528 BHFH004528	EHFH004531 BHFH004531
50	EHFH005021 BHFH005021	EHFH005025 BHFH005025	EHFH005028 BHFH005028	EHFH005031 BHFH005031
55	EHFH005521 BHFH005521	EHFH005525 BHFH005525	EHFH005528 BHFH005528	EHFH005531 BHFH005531
60	EHFH006021 BHFH006021	EHFH006025 BHFH006025	EHFH006028 BHFH006028	EHFH006031 BHFH006031
70	EHFH007021 BHFH007021	EHFH007025 BHFH007025	EHFH007028 BHFH007028	EHFH007031 BHFH007031
80	EHFH008021 BHFH008021	EHFH008025 BHFH008025	EHFH008028 BHFH008028	EHFH008031 BHFH008031
90	EHFH009021 BHFH009021	EHFH009025 BHFH009025	EHFH009028 BHFH009028	EHFH009031 BHFH009031
100	EHFH010021 BHFH010021	EHFH010025 BHFH010025	EHFH010028 BHFH010028	EHFH010031 BHFH010031
110	EHFH011021 BHFH011021	EHFH011025 BHFH011025	EHFH011028 BHFH011028	EHFH011031 BHFH011031
120	EHFH012021 BHFH012021	EHFH012025 BHFH012025	EHFH012028 BHFH012028	EHFH012031 BHFH012031
130	EHFH013021 BHFH013021	EHFH013025 BHFH013025	EHFH013028 BHFH013028	EHFH013031 BHFH013031

140	EHFH014021 BHFH014021	EHFH014025 BHFH014025	EHFH014028 BHFH014028	EHFH014031 BHFH014031
15-40	EHFH154021 BHFH154021	EHFH154025 BHFH154025	EHFH154028 BHFH154028	EHFH154031 BHFH154031
45-80	EHFH458021 BHFH458021	EHFH458025 BHFH458025	EHFH458028 BHFH458028	EHFH458031 BHFH458031
90-140	EHFH901421 BHFH901421	EHFH901425 BHFH901425	EHFH901428 BHFH901428	EHFH901431 BHFH901431

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski