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, 2022-05-18

CERTIFICATE OF FREE SALE No. 256/2022

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 pursuant to art. 67 of the Act of May 20, 2010 on medical devices (Journal of Laws of 2021, items 1565) 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-reamers / K-reamers	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261KRHDB

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 MEDYCZNYCH I PRODUKTÓW BIOBÓJCZYCH * WYROBÓW * 2 *

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Urząd Rejestracji
Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych
Al. Jerozolimskie 181C, 02–222 Warszawa tel. +48 22 492–11–00, fax +48 22 492–11–09
NIP 521–32–14–182 REGON 015249601

Attachment to the Free Sale Certificate number 256/2022 from 18.05.2022

TRADE NAME OF DEVICE: : Endostar K-reamers / K-reamers

TYPE:

ISO	Kod/*code*			
	21 mm	25 mm	28 mm	31 mm
6	EKRH000621 BKRH000621	EKRH000625 BKRH000625	EKRH000628 BKRH000628	EKRH000631 BKRH000631
8	EKRH000821 BKRH000821	EKRH000825 BKRH000825	EKRH000828 BKRH000828	EKRH000831 BKRH000831
10	EKRH001021 BKRH001021	EKRH001025 BKRH001025	EKRH001028 BKRH001028	EKRH001031 BKRH001031
15	EKRH001521 BKRH001521	EKRH001525 BKRH001525	EKRH001528 BKRH001528	EKRH001531 BKRH001531
20	EKRH002021 BKRH002021	EKRH002025 BKRH002025	EKRH002028 BKRH002028	EKRH002031 BKRH002031
25	EKRH002521 BKRH002521	EKRH002525 BKRH002525	EKRH002528 BKRH002528	EKRH002531 BKRH002531
30	EKRH003021 BKRH003021	EKRH003025 BKRH003025	EKRH003028 BKRH003028	EKRH003031 BKRH003031
35	EKRH003521 BKRH003521	EKRH003525 BKRH003525	EKRH003528 BKRH003528	EKRH003531 BKRH003531
40	EKRH004021 BKRH004021	EKRH004025 BKRH004025	EKRH004028 BKRH004028	EKRH004031 BKRH004031
45	EKRH004521 BKRH004521	EKRH004525 BKRH004525	EKRH004528 BKRH004528	EKRH004531 BKRH004531
50	EKRH005021 BKRH005021	EKRH005025 BKRH005025	EKRH005028 BKRH005028	EKRH005031 BKRH005031
55	EKRH005521 BKRH005521	EKRH005525 BKRH005525	EKRH005528 BKRH005528	EKRH005531 BKRH005531
60	EKRH006021 BKRH006021	EKRH006025 BKRH006025	EKRH006028 BKRH006028	EKRH006031 BKRH006031
70	EKRH007021 BKRH007021	EKRH007025 BKRH007025	EKRH007028 BKRH007028	EKRH007031 BKRH007031
80	EKRH008021 BKRH008021	EKRH008025 BKRH008025	EKRH008028 BKRH008028	EKRH008031 BKRH008031
15-40	EKRH154021 BKRH154021	EKRH154025 BKRH154025	EKRH154028 BKRH154028	EKRH154031 BKRH154031
45-80	EKRH458021 BKRH458021	EKRH458025 BKRH458025	EKRH458028 BKRH458028	EKRH458031 BKRH458031
90-140	EKRH901421 BKRH901421	EKRH901425 BKRH901425	EKRH901428 BKRH901428	EKRH901431 BKRH901431

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices
Sebastian Migdalski