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. 258/2022

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 NiTi K-files / NiTi K-files	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261NKHD5

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 WYROBÓW MEDYCZNYCH I PRODUKTÓW BIOBÓJCZYCH * 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 258/2022 from 18.05.2022

TRADE NAME OF DEVICE: Endostar NiTi K-files / NiTi K-files

TYPE:

ISO	Kod/*code*			
	21 mm	25 mm	28 mm	31 mm
15	ENKH001521 BNKH001521	ENKH001525 BNKH001525	ENKH001528 BNKH001528	ENKH001531 BNKH001531
20	ENKH002021 BNKH002021	ENKH002025 BNKH002025	ENKH002028 BNKH002028	ENKH002031 BNKH002031
25	ENKH002521 BNKH002521	ENKH002525 BNKH002525	ENKH002528 BNKH002528	ENKH002531 BNKH002531
30	ENKH003021 BNKH003021	ENKH003025 BNKH003025	ENKH003028 BNKH003028	ENKH003031 BNKH003031
35	ENKH003521 BNKH003521	ENKH003525 BNKH003525	ENKH003528 BNKH003528	ENKH003531 BNKH003531
40	ENKH004021 BNKH004021	ENKH004025 BNKH004025	ENKH004028 BNKH004028	ENKH004031 BNKH004031
45	ENKH004521 BNKH004521	ENKH004525 BNKH004525	ENKH004528 BNKH004528	ENKH004531 BNKH004531
50	ENKH005021 BNKH005021	ENKH005025 BNKH005025	ENKH005028 BNKH005028	ENKH005031 BNKH005031
55	ENKH005521 BNKH005521	ENKH005525 BNKH005525	ENKH005528 BNKH005528	ENKH005531 BNKH005531
60	ENKH006021 BNKH006021	ENKH006025 BNKH006025	ENKH006028 BNKH006028	ENKH006031 BNKH006031
70	ENKH007021 BNKH007021	ENKH007025 BNKH007025	ENKH007028 BNKH007028	ENKH007031 BNKH007031
80	ENKH008021 BNKH008021	ENKH008025 BNKH008025	ENKH008028 BNKH008028	ENKH008031 BNKH008031
15-40	ENKH154021 BNKH154021	ENKH154025 BNKH154025	ENKH154028 BNKH154028	ENKH154031 BNKH154031
45-80	ENKH458021 BNKH458021	ENKH458025 BNKH458025	ENKH458028 BNKH458028	ENKH458031 BNKH458031

This attachment is valid only with the original certificate.

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