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. 257/2022

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

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 PRZEZNACZONYCH DO WYROBÓW MEDYCZNYCH * 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 257/2022 from 18.05.2022

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

TYPE:

ISO	Kod/*code*			
	21 mm	25 mm	28 mm	31 mm
15	ENRH001521 BNRH001521	ENRH001525 BNRH001525	ENRH001528 BNRH001528	ENRH001531 BNRH001531
20	ENRH002021 BNRH002021	ENRH002025 BNRH002025	ENRH002028 BNRH002028	ENRH002031 BNRH002031
25	ENRH002521 BNRH002521	ENRH002525 BNRH002525	ENRH002528 BNRH002528	ENRH002531 BNRH002531
30	ENRH003021 BNRH003021	ENRH003025 BNRH003025	ENRH003028 BNRH003028	ENRH003031 BNRH003031
35	ENRH003521 BNRH003521	ENRH003525 BNRH003525	ENRH003528 BNRH003528	ENRH003531 BNRH003531
40	ENRH004021 BNRH004021	ENRH004025 BNRH004025	ENRH004028 BNRH004028	ENRH004031 BNRH004031
45	ENRH004521 BNRH004521	ENRH004525 BNRH004525	ENRH004528 BNRH004528	ENRH004531 BNRH004531
50	ENRH005021 BNRH005021	ENRH005025 BNRH005025	ENRH005028 BNRH005028	ENRH005031 BNRH005031
55	ENRH005521 BNRH005521	ENRH005525 BNRH005525	ENRH005528 BNRH005528	ENRH005531 BNRH005531
60	ENRH006021 BNRH006021	ENRH006025 BNRH006025	ENRH006028 BNRH006028	ENRH006031 BNRH006031
70	ENRH007021 BNRH007021	ENRH007025 BNRH007025	ENRH007028 BNRH007028	ENRH007031 BNRH007031
80	ENRH008021 BNRH008021	ENRH008025 BNRH008025	ENRH008028 BNRH008028	ENRH008031 BNRH008031
15-40	ENRH154021 BNRH154021	ENRH154025 BNRH154025	ENRH154028 BNRH154028	ENRH154031 BNRH154031
45-80	ENRH458021 BNRH458021	ENRH458025 BNRH458025	ENRH458028 BNRH458028	ENRH458031 BNRH458031

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski