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. 252/2022

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 H-Files/ NiTi H-Files	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261NHHCU

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, 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 252/2022 from 18.05.2022

TRADE NAME OF DEVICE: Endostar NiTi H-Files/ NiTi H-Files

TYPE:

ISO	Kod/*code*			
	21 mm	25 mm	28 mm	31 mm
15	ENHH001521 BNHH001521	ENHH001525 BNHH001525	ENHH001528 BNHH001528	ENHH001531 BNHH001531
20	ENHH002021 BNHH002021	ENHH002025 BNHH002025	ENHH002028 BNHH002028	ENHH002031 BNHH002031
25	ENHH002521 BNHH002521	ENHH002525 BNHH002525	ENHH002528 BNHH002528	ENHH002531 BNHH002531
30	ENHH003021 BNHH003021	ENHH003025 BNHH003025	ENHH003028 BNHH003028	ENHH003031 BNHH003031
35	ENHH003521 BNHH003521	ENHH003525 BNHH003525	ENHH003528 BNHH003528	ENHH003531 BNHH003531
40	ENHH004021 BNHH004021	ENHH004025 BNHH004025	ENHH004028 BNHH004028	ENHH004031 BNHH004031
45	ENHH004521 BNHH004521	ENHH004525 BNHH004525	ENHH004528 BNHH004528	ENHH004531 BNHH004531
50	ENHH005021 BNHH005021	ENHH005025 BNHH005025	ENHH005028 BNHH005028	ENHH005031 BNHH005031
55	ENHH005521 BNHH005521	ENHH005525 BNHH005525	ENHH005528 BNHH005528	ENHH005531 BNHH005531
60	ENHH006021 BNHH006021	ENHH006025 BNHH006025	ENHH006028 BNHH006028	ENHH006031 BNHH006031
70	ENHH007021 BNHH007021	ENHH007025 BNHH007025	ENHH007028 BNHH007028	ENHH007031 BNHH007031
80	ENHH008021 BNHH008021	ENHH008025 BNHH008025	ENHH008028 BNHH008028	ENHH008031 BNHH008031
15-40	ENHH154021 BNHH154021	ENHH154025 BNHH154025	ENHH154028 BNHH154028	ENHH154031 BNHH154031
45-80	ENHH458021 BNHH458021	ENHH458025 BNHH458025	ENHH458028 BNHH458028	ENHH458031 BNHH458031

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski