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. 253/2022

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

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.



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 253/2022 from 18.05.2022

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

TYPE:

ISO	Kod/*code*			
	21 mm	25 mm	28 mm	31 mm
10	ENFH001021 BNFH001021	ENFH001025 BNFH001025	ENFH001028 BNFH001028	ENFH001031 BNFH001031
15	ENFH001521 BNFH001521	ENFH001525 BNFH001525	ENFH001528 BNFH001528	ENFH001531 BNFH001531
20	ENFH002021 BNFH002021	ENFH002025 BNFH002025	ENFH002028 BNFH002028	ENFH002031 BNFH002031
25	ENFH002521 BNFH002521	ENFH002525 BNFH002525	ENFH002528 BNFH002528	ENFH002531 BNFH002531
30	ENFH003021 BNFH003021	ENFH003025 BNFH003025	ENFH003028 BNFH003028	ENFH003031 BNFH003031
35	ENFH003521 BNFH003521	ENFH003525 BNFH003525	ENFH003528 BNFH003528	ENFH003531 BNFH003531
40	ENFH004021 BNFH004021	ENFH004025 BNFH004025	ENFH004028 BNFH004028	ENFH004031 BNFH004031
45	ENFH004521 BNFH004521	ENFH004525 BNFH004525	ENFH004528 BNFH004528	ENFH004531 BNFH004531
50	ENFH005021 BNFH005021	ENFH005025 BNFH005025	ENFH005028 BNFH005028	ENFH005031 BNFH005031
55	ENFH005521 BNFH005521	ENFH005525 BNFH005525	ENFH005528 BNFH005528	ENFH005531 BNFH005531
60	ENFH006021 BNFH006021	ENFH006025 BNFH006025	ENFH006028 BNFH006028	ENFH006031 BNFH006031
70	ENFH007021 BNFH007021	ENFH007025 BNFH007025	ENFH007028 BNFH007028	ENFH007031 BNFH007031
80	ENFH008021 BNFH008021	ENFH008025 BNFH008025	ENFH008028 BNFH008028	ENFH008031 BNFH008031
15-40	ENFH154021 BNFH154021	ENFH154025 BNFH154025	ENFH154028 BNFH154028	ENFH154031 BNFH154031
45-80	ENFH458021 BNFH458021	ENFH458025 BNFH458025	ENFH458028 BNFH458028	ENFH458031 BNFH458031

This attachment is valid only with the original certificate.

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