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. 254/2022

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 Unique S-files	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261SFHDF

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 254/2022 from 18.05.2022

TRADE NAME OF DEVICE: Endostar Unique S-files

TYPE:

ISO	Kod/*code*	
	21 mm	25 mm
12.5	EUSF001221	EUSF001225 BUSF001225
17.5	EUSF001721	EUSF001725 BUSF001725
22.5	EUSF002221	EUSF002225 BUSF002225
12.5-22.5	EUSF122221	EUSF122225 BUSF122225

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski