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, 2022-07-06

CERTIFICATE OF FREE SALE No. 407 / 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 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 z 5.5.2017, p. 1) pursuant to art. 30 of the Act of April 7, 2022 on medical devices (Journal of Laws of 2022, items 974) 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 Finger Spreaders/ NiTi Finger Spreaders	According to attachment
Notified body certificate number	Not applicable
Basic UDI-DI code	5900261STDEH

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 I PRODUKTÓW BIOBÓJCZYCH WYROBÓW MEDYCZNYCH

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

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Attachment to the Free Sale Certificate number 407/2022 from 06.07.2022

TRADE NAME OF DEVICE: Endostar NiTi Finger Spreaders

Available codes of instruments:

ISO	code
15	ESTD001525 BSTD001525
20	ESTD002025 BSTD002025
25	ESTD002525 BSTD002525
30	ESTD003025 BSTD003025
35	ESTD003525 BSTD003525
40	ESTD004025 BSTD004025
15-40	ESTD154025 BSTD154025

This attachment is valid only with the original certificate.

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski