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

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Warsaw, 2019-08-14

CERTIFICATE OF FREE SALE No. 419/2019

In reference to application for a free sale certificate made by the

CHEMA-ELEKTROMET Spółdzielnia Pracy
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
GUTAP ORANGE Gutta-percha orange solvent	-
Alternative name of the device	
ENDOSTAR GUTTA CLEANER Gutta-percha orange solvent	

manufactured by:

CHEMA-ELEKTROMET Spółdzielnia Pracy
ul. Przemysłowa 9, 35-105 Rzeszów, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. The medical device CE marked in conformity with the act of 20th May 2010 on medical devices (Official Journal of Laws from 2019, item 175) which implements Directive 93/42/EEC can be placed on the market and put into service in the territory of Republic of Poland. Export of the above product is not prohibited.

PREZES URZĘDU REJESTRACJI PRODUKTÓW LECZNICZYCH, WYROBÓW MEDYCZNYCH I PRODUKTÓW BIOBÓJCZYCH

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

Certificate of Free Sale is issued pursuant to the provisions of the art. 67 of the Act on Medical Devices of 20th May 2010 (Official Journal of Laws from 2019, item 175)