



CERTIFICATE

EC No. 1434-MDD-052/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

HAGMED Spółka z o.o.
Spółka Komandytowa
32 Tomaszowska Str. 96-200 Rawa Mazowiecka Poland

for the design, manufacture and final inspection of
medical devices, class IIb

Resectoscope electrodes

The list of medical devices covered by this certificate is given in the Annex No. 1

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2019-04-15 to 2024-04-14

The date of issue of the Certificate: 2019-04-15



Application No.: 096/2018
Module H


mgr Anna Wyroba
Vice-President



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Certificate No. **1434-MDD-052/2019**
Issued under the contract no. **MD-40/2018**
Bears the PCBC hologram
Warsaw, 15.04.2019



ANNEX No. 1
VALID ONLY WITH CERTIFICATE
N. 1434-MDD-052/2019

The list of medical devices covered by the certificate

Type of electrode	Models
Electrodes for electro-resection of the prostate	STO-124; STO-2124; STO-2124-G; STO-224; STO-2224; STO-2224-G; STO-624; STO-2624; STO-2624-G; STO-1424; OLY-124; OLY-2124; OLY-2124-G; OLY-224; OLY-224-L; OLY-2224; OLY-2224-L; OLY-2224-G; OLY-2224-LL; OLY-3224; OLY-624; OLY-2624; OLY-2624-G; OLY-1424
Electrodes for electro-incision of the prostate	STO-324; STO-3324; STO-4324; OLY-324; OLY-3324; OLY-4324; OLY-5324
Electrodes for electro-coagulation of the prostate	STO-424; STO-2424; STO-524; STO-2524; STO-724; STO-2724; STO-924; STO-2924; OLY-424; OLY-424-L; OLY-2424; OLY-2424-L; OLY-524; OLY-2524; OLY-724; OLY-2724; OLY-924; OLY-2924;
Electrodes for electro-vaporization of the prostate	STO-824; STO-1024; STO-1124; STO-1224; OLY-824; OLY-1024; OLY-1124; OLY-1224;



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Annex to certificate No. **1434-MDD-052/2019**
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