

GMED certifies that the quality management system developed by

Apyx Medical Corporation

5115 Ulmerton Rd.

Clearwater, FL 33760 UNITED STATES

Facility identifier (REPs-generated) : F004205

for the activities

Conception et fabrication de dispositifs électrochirurgicaux utilisés dans des procédures (voir détail addendum)

Design and Manufacture of Electrosurgical Devices used in Open and Laparoscopic Procedures (see details on addendum)

performed on the location(s) of

Apyx Medical Corporation 5115 Ulmerton Rd. Clearwater, FL 33760 USA

Apyx-Bulgaria Ltd. Boul. Tsarigradsko shose, 133, BIC IZOT, Building 3, fl.3 and fl.5, Sofia; 1784 BGR

has been audited and found to conform to the requirements of the international standard ISO 13485 : 2016 and following regulatory requirements

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

Début de validité / Effective date June 2nd, 2021 (included)

Valable jusqu'au / Expiry date : March 18th, 2023 (included)

Etabli le / Issued on : June 2nd, 2021



GMED is authorised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of GMED Certification
The validity of this certificate can be verified on www.gmed.fr

Modifie le certificat 36646-0



DocuSigned by:

Beatrice Lys

EF33BDA9BAA04A3...

On behalf of the President

Béatrice LYS

Technical Director

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites :

French version:

Conception et fabrication de dispositifs électrochirurgicaux utilisés dans des procédures ouvertes et laparoscopiques destinées à être utilisées avec des générateurs électrochirurgicaux compatibles pour la délivrance d'énergie de radiofréquence et / ou de plasma d'hélium pour la coupe, la coagulation et l'ablation de tissus mous.

English version:

Design and Manufacture of Electrosurgical Devices used in Open and Laparoscopic Procedures intended to be used with compatible electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue.

Apyx Medical

5115 Ulmerton Rd.,
Clearwater, FL, 33760 USA

Management, conception, achat, production, service, distribution, installation, QA, réglementaire /
Management, Design, purchasing, Production, servicing, storage, distribution, installation, QC, RA

Apyx-Bulgaria Ltd.

Facility ID : F005588

Boul. Tsarigradsko shose, 133, BIC IZOT, Building 3, fl.3 and fl.5,
Sofia; 1784 Bulgaria

Production, entretien et contrôle final de pièces à main, générateurs
et assembleur de commutateurs au pied et régulateurs de gaz /
*Production, Servicing and final Control of Handpieces, Generators,
and Assembler of Foot Switches and Gas Regulators*

2 sites / 2 sites



DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President
Béatrice LYS
Technical Director**