

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, fabrication et reconditionnement de dispositifs électrochirurgicaux utilisés dans les procédures (voir détail addendum)

Design, Manufacture and refurbishment 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, floors 1, 2, 3, 4 and 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. 665/2022 RDC ANVISA n. 551/2021 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 May 7th, 2025 (included)

Valable jusqu'au / Expiry date : May 6th, 2028 (included)

Etabli le / Issued on : May 1st, 2025



GMED is recognised 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

Renouvelle le certificat 36646-2

DocuSigned by:
Béatrice LYS
EF33BDA9BAA0
GMED GROUPE LNE
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, fabrication et reconditionnement de dispositifs électrochirurgicaux utilisés dans les procédures de chirurgies générales et laparoscopiques, destinés à être utilisés avec des générateurs électrochirurgicaux compatibles pour délivrer de l'énergie radiofréquence et/ou du plasma (tel que l'hélium ou l'argon) pour la coupe, la coagulation et l'ablation des tissus mous (y compris, mais sans s'y limiter, les tissus mous sous-cutanés et dermiques). Conception de systèmes de liposuction et d'instruments (réutilisables) de liposuction à des fins de remodelage esthétique du corps.

English version:

Design, Manufacture and refurbishment 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 plasma (such as helium or argon) for cutting, coagulation and ablation of soft tissue (including but not limited to subcutaneous and dermal soft tissues). Design of Liposuction Systems and liposuction instrument (reusable) for the purpose of aesthetic body contouring

Apyx Medical

5115 Ulmerton Rd.,
Clearwater, FL, 33760 USA

Management, conception, achat, production, service, distribution, installation, assurance qualité, réglementaire, et reconditionnement / *Management, Design, purchasing, Production, servicing, storage, distribution, installation, Quality Control, Regulatory Affairs, Refurbishment*

Apyx-Bulgaria Ltd.

Facility ID : F005588

Boul. Tsarigradsko shose, 133, BIC IZOT, Building 3, floors 1, 2, 3, 4 and 5, Sofia, 1784 Bulgaria

Production, conception, achat, service, distribution, installation, assurance qualité, et reconditionnement / *Production, Design, Purchasing, Servicing, Storage, Distribution, installation, Quality Control, and Refurbishment.*

2 sites / 2 sites

DocuSigned by:

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**On behalf of the President
Beatrice Lys
Technical Director**