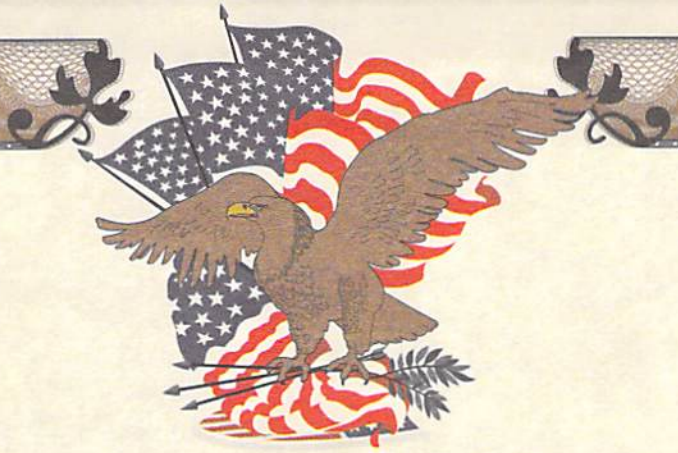

Certificate of Medical Device Master File (MAF)

Service Period
June 1, 2023 – May 31, 2024

This certifies that:

Bio-Vac España, S.A.
Calle Benjamin Franklin, 25 - Parque Tecnologico 46117 Bétera, Valencia
Spain

is a Medical Device Master File holder with the U.S. Food and Drug Administration pursuant to part 814 of Title 21, US Code of Federal Regulations, such filing having been verified as currently effective on the date hereof by Registrar Corp.

Medical Device Master File Number: **3779**
Subject: **POROUS SINTERED BEAD COATINGS**

Registrar Corp will confirm that such filing remains effective upon request and presentation of this certificate until May 31, 2024, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Filing of a Medical Device Master File does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of filing of Medical Device Master File is misleading. The U.S. Food and Drug Administration does not issue a certificate of Medical Device Master Files. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lemarz
Executive Director
Registrar Corp
Dated: November 30, 2023

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgement Letter

11/30/2023

David Lennarz, Agent
Registrar Corp
144 Research Drive
Hampton, VA 23666
UNITED STATES

Dear David Lennarz:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: MAF3779
Received: 11/29/2023
Applicant: Bio-Vac Espana S.A.
Device: Porous Sintered Bead Coatings

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Registrar Corp
144 Research Drive, Hampton, Virginia 23666 USA
Phone: +1-757-224-0177 * Fax: +1-757-224-0179 * Email: info@registrarcorp.com * Website: www.registrarcorp.com

November 30, 2023

Bio-Vac España, S.A.
Calle Benjamin Franklin, 25 - Parque
Tecnologico 46117 Bétera, Valencia
Spain

Re: Medical Device Master Files (MAFs)

Good Day:

We attach the Certificate of Medical Device Master File (MAF) issued by Registrar Corp verifying that Bio-Vac España, S.A. is a Medical Device Master File holder with the U.S. Food and Drug Administration.

Filing of a Medical Device Master File does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of filing of Medical Device Master File is misleading. The U.S. Food and Drug Administration does not issue or recognize certificates of Medical Device Master Files.

Please contact us if you have any additional questions or need additional help with FDA compliance.

Sincerely,

David Lennarz
President