

UNITED STATES OF AMERICA

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Respondent and the Bureau of Competition executed an agreement (Agreement Containing Consent Order or "Consent Agreement") containing (1) an admission by Respondent of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules and (4) a proposed Decision and Order and Order to Maintain Assets

The Commission considered the matter and determined that it had reason to believe that Respondent have violated the said Acts, and that a complaint should issue against charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days. (130)(or)3 (dt)TJA (h)-1 (n)]T or a p publisd i apld2sio r iic(c)4 (n)-4 (cc)4 Tmedi a

- F. “Acquisition Agreement” means the *Stock Purchase Agreement* by and between Grifols Shared Services North America, Inc., Biotest US Corporation, Biotest AG, and ~~sole~~ the purposes of Section 1.7 of the *Stock Purchase Agreement* as guarantor, Grifols, S.A. dated December 22, 2017, and the *Amendment* [amendment insert] dated [insert] that were submitted by the Respondents to the Commission in this matter. ~~h~~ Acquisition Agreements contained in NonPublic Appendix I.
- G. “Acquisition Date” means the date on which Respondent acquire fifty percent (50%) or more of the outstanding voting securities of Biotest US
- H. “ADMA” means ADMA Biologics, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 65 State Route 17, Ramsey, New Jersey 07446.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the operation of the Business of Plasma Donor Center. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Applicant Plasma” means human plasma collected from any of the Plasma Donor Center Divestiture Facilities that has not been fully tested and cleared within the Respondents’ donor management system (Blood Establishment Computer System) for subsequent use or distribution.
- K. “Blood Establishment Computer System” means the computer hardware, computer software, peripheral devices, networks, and documentation (e.g., users manuals and standard operating procedures) required by the FDA pursuant to 21 CFR 211.68, 606.100(b), and 606.100 that apply to blood establishment validation systems and any other components of such a system required by the FDA in order to (i) ensure the proper diagnosis of disease or other conditions in donors of human blood or blood components or (ii) to prevent disease by preventing the release of unqualified blood and blood components.
- L. “Business” means the activities related to the collection and processing of human blood and blood components (e.g., plasma) conducted at Plasma Donor Center
- M. “Closing Date” means, as to each Plasma Donor Center Divestiture Facility the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets to such Plasma Donor Center Divestiture Facility to an Acquirer pursuant to this Order.
- N. “Collection Materials” means materials used under the standard operating procedures for blood collection, handling, and processing at each of the Plasma Donor Center Divestiture Facilities (e.g., plasma collection tubes)

- O. “Current Operating Condition” means that, as of the date of delivery to the Acquirer, the machine meets or exceeds all current operational, functional, and productive capabilities required to perform plasmapheresis.
- P. “Disposable Medical Supplies” means general medical products regularly used in the conduct of the Business of a Plasma Donor Center that are intended for one or temporary use (e.g., gloves, needles, bandages, paper products, syringes, and wipes).
- Q. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- R. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- S. “Government Entity” means any Federal, state, local, or non-U.S. government, any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- T. “Fixtures and Equipment” means all furniture, fixtures, furnishings, machinery, equipment, supplies and other tangible personal property used or held for use in the operation of the Business of each of the Plasma Donor Center Divestiture Facilities respectively, or if leased, the Respondents’ leasehold interest therein.
- U. “Kedplasma” means (i) Kedplasma LLC, wholly-owned subsidiary of Kedrion S.p.a. and a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive office and principal place of business located at Parker Plaza, 400 Kelby Street, Fort Lee, New Jersey 07024; Kedrion S.p.a, a corporation organized, existing, and doing business under and by virtue of the laws of the Italian Republic with its registered office located at Località Ai Conti – 55051 Barga (Lucca) - frazione Castelvecchio Pascoli, Italy and any other subsidiary of Kedrion S.p.a.
- V. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- W. “Monitor” means any monitor appointed pursuant to Paragraph IV of this Order or Paragraph III of the related Order to Maintain Assets.
- X. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- Y. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- Z. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.

- AA. "Ownership Interest" means any voting or nonvoting stock, share capital, equity, notes convertible into any voting or nonvoting stock, or other interest in an entity.
- BB. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- CC. "Plasma Donor Center(s)" means a facility used for the collection of whole blood or plasma from human donors that operates in accordance with FDA rules related to the evaluation of the eligibility of potential donors and to the storing, processing, tracking, testing, and shipping of human blood or blood components for further manufacturing and use in blood or plasma-based therapies.
- DD. "Plasma Donor Center Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the operation of the Business of a Plasma Donor Center.
- EE. "Plasma Donor Center Confidential Business Information" means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the conduct of the Business of the Plasma Donor Center Divestiture Facilities. The term "Plasma Donor Center Confidential Business Information" *excludes*, and Respondents are not required to submit the following information to an Acquirer:
1. information relating to a Respondent's general business strategies or practices that does not discuss with particularity the Business of a particular Plasma Donor Center Divestiture Facility
 2. information specifically excluded from the Plasma Donor Center Divestiture Assets conveyed to the Acquirer
 3. information that is contained in documents, records, or books of a Respondent that is provided to an Acquirer by a Respondent

6. at the Acquirer's option either (i) all plasmapheresis machines used or held for use in the operation of the Business at each respective Plasma Donor Center Divestiture Facility (which machines shall be delivered to the Acquirer in Current Operating Condition), or (ii) a license for an interim period to use plasmapheresis machines used or held for use in the operation of the Business at each respective Plasma Donor Center Divestiture Facility (which machines shall be provided to the Acquirer in Current Operating Condition) for a time sufficient to allow the Acquirer to transition to the Acquirer's own plasmapheresis machines
7. at least two (2) weeks supply (in the ordinary course of business) of Collection Materials at each Plasma Donor Center Divestiture Facility
8. at least two (2) weeks supply (in the ordinary course of business) of Disposable Medical Supplies at each Plasma Donor Center Divestiture Facility
9. at least two (2) weeks supply (in the ordinary course of business) of janitorial supplies, including such supplies as are required to prevent exposure to potentially infectious materials;
10. all donor records and registries related to the blood or blood component (plasma) donations made at the particular Plasma Donor Center Divestiture Facility including any records made by personnel at that Plasma Donor Center Divestiture Facility relating to the collection of plasma from a donor
11. all computers and computer equipment, printers, software and databases, routers, servers, switches and timeclocks and documentation related to any of the foregoing used or held for use in the operation of the Business of each Plasma Donor Center Divestiture Facility (all cabling within each center shall remain in place), which shall also include access to any computer databases or donor information connected or related to each Plasma Donor Center Divestiture Facility at the corporate level held outside the respective Plasma Donor Center Divestiture Facility;
12. at the Acquirer's option a license for an interim period of the Blood Establishment Computer System that was in use in connection with the operation of each Plasma Donor Center Divestiture Facility prior to the Acquisition for a time sufficient to allow the Acquirer to

- g. employment status (i.e., active or on leave or disability; fulltime or part-time);
 - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees and
3. at the Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

KK. "Relevant Geographic Markets" means the following:

- 1. City of Lincoln, Nebraska;
- 2. City of Augusta, Georgia; and
- 3. City of Youngstown, Ohio.

LL. "Remedial Agreement(s)" means the following:

- 1. any agreement between a Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof for services and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
- 2. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Plasma Donor Center Divestiture Facility(ies) or other Order requirement to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
- 3. any agreement between a Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by that Respondent to supply specified products or components thereof for services and that has been approved by the Commission to accomplish the requirements of this Order; and/or
- 4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Plasma Donor Center Divestiture Facility(ies) or other Order requirement to the benefit of an Acquirer that has been

Commission may direct Respondent or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of Plasma Donor Center Divestiture Assets to Kedplasma (including, but not limited to, entering into additional agreements or

c. applicable Law;

5. not disclose or convey any Plasma Donor Center Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by that Acquirer, (iii) staff of the Commission to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law
6. not provide, disclose or otherwise make available, directly or indirectly, any Plasma Donor Center Confidential Business Information to the employees associated with the Plasma Donor Centers that are being retained by the Respondents
7. institute procedures and requirements to ensure that the described employees
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Plasma Donor Center Confidential Business Information in contravention of this Order to Maintain Assets
 - b. do not solicit, access or use any Plasma Donor Center Confidential Business Information that they are prohibited from receiving for any reason or purpose.

E. Respondents shall

1. not later than ten (10) days after a request from the Acquirer, provide the Acquirer with the Plasma Donor Center Employee Information;
2. for a period of twelve (12) months after the Closing Date, provide the Acquirer with the opportunity to enter into employment contracts with the employees that work in the locations of each of the Plasma Donor Center Divestiture
3. until the Closing Date, provide all of the above

- d. ensure the ~~ass~~ related to each Plasma Donor Center

- H. The purpose of the divestiture of the Plasma Donor Center Divestiture Assets related obligations imposed on the Respondent by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Plasma Donor Center Divestiture Facility
 2. to create a viable and effective competitor that is independent of Respondent's Business of each Plasma Donor Center Divestiture Facility and
 3. to remedy the lessening of competition resulting from the divestiture

1. The Monitor shall have the power and authority to monitor each Respondent compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;
 2. The Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission; and
 3. The Monitor shall serve until Respondents complete each of the divestitures required by this Order and complete any transitional services required to be provided to an Acquirer under this Order or related Remedial Agreement provided, however, that the Monitor's service shall not extend more than two (2) years after the Order Date unless the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.
- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Order.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondent on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Respondent shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after

the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

- I. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Responders, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Responders have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Responders of the identity of any proposed Divestiture Trustee, Responders shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Responders shall execute a trust agreement that, subject to the prior approval (e)4 son tova (ov 0 T7 (e)-(va (

4. The Divestiture Trustee shall use commercial reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustees consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustees consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustees duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

VI.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Business associated with those Divestiture Products;

provided, however Re

provided further, however, that pursuant to this Paragraph, Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VII.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement, any modification or amendment of any Remedial Agreement made without the approval of the Commission or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VIII.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition Date, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition Date occurred including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov

- B. Within five (5) days of each Closing Date, Respondent shall submit to Commission staff a letter certifying the date on which that particular divestiture o

X.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters address, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of that Respondent related to compliance with this Order, which copies shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on the date ten (10) years after

NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT
[Cover Page]

[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II. A
AGREEMENTS RELATED TO THE
PLASMA DONOR CENTER DIVESTITURE ASSETS
[Cover Page]